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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

Spielberg
X Roland (cont'd)
Stinky
Hunt

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamek, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Counsel

Associate Counsel

Administrator

Transcript of evidence
for
October 26, 1983

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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Wednesday, the 26th
day of October, 1983.

- - - - -

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

- - - - -

APPEARANCES:

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	Nurses' Association of Ontario
	and 35 Registered Nurses at
	The Hospital for Sick Children

(Cont'd)



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J. SHINEHOFT	Counsel for Lorie Pacsai and Kevin Garnet (parents of deceased child Kevin Pacsai)

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A/DM/ak

---Upon commencing at 10:00 a.m.

DR. STEPHEN PAUL SPIELBERG, Resumed

THE COMMISSIONER: Yes, Mr. Roland.

MR. ROLAND: Mr. Commissioner, before we begin with Dr. Spielberg; yesterday we put in an exhibit with respect to Kristin Inwood and the blood sample that went to Toxicology.

MS. CRONK: Virology.

MR. ROLAND: I'm sorry, Virology. It is our understanding that with respect to that sample that by the time it got to Forensic Science it was a serum sample and not a blood sample, that in Virology the serum had been extracted from the blood and that some tests had been done on that serum sample for the purposes that it had been submitted to Virology. It is our understanding that it was a serum sample.

THE COMMISSIONER: Yes.

MR. ROLAND: We have as well for this morning two exhibits to put in; the first is entitled "Medication Errors: Causes and Prevention". Actually the exhibit is an extract I believe from a publication, from a book publication and we have extracted Chapter 2 entitled: "Published Medication Error Studies" and it is a review of the number of



1
2 studies of various institutions in the United States
3 concerning medication errors. I ask that be the
4 next exhibit.

5 THE COMMISSIONER: Yes, Exhibit 222.

6 ---EXHIBIT NO. 222: Extract from publication
7 "Medication Errors: Causes
8 and Prevention".

9 MR. ROLAND: Then the paper entitled
10 "Prevention of Medication Error" by Wang, and
11 Turndorf, and it is published in the New York State
12 Journal of Medicine, March, 1981. I ask that be the
13 next exhibit.

14 THE COMMISSIONER: Exhibit 223.

15 ---EXHIBIT NO. 223: Paper on "Prevention of
16 Medication Error" published
17 in New York State Journal of
18 Medicine, March, 1981.

19 EXAMINATION BY MR. ROLAND: (Continued)

20 Q. Dr. Speilberg, before we
21 begin a discussion on the literature and your
22 experience with respect to medication errors, could
23 we review just for a moment your particular qualifica-
24 tions concerning the subject of medication errors.
25 I understand that for a period of approximately
six years you have been Chairman of Pharmacy Committees



1
2 reviewing errors and incident reports, both at
3 Johns Hopkins and at the Hospital for Sick Children.

4 A. Yes, that is correct.

5 Q. And that you have been a
6 special consultant to the National Institute of
7 Health in the United States concerning the subject
8 matter of pediatric drug surveillances and medication
9 errors.

9 A. Yes, that is correct, yes.

10 Q. Are you currently a special
11 consultant to that Institute?

12 A. We recently completed a site
13 visit examining one such drug surveillance system
14 several months ago, yes.

15 MR. ROLAND: Now, Mr. Commissioner,
16 before we get into the subject matter of the papers
17 I want to take Dr. Spielberg through the papers so
18 that we can understand them. Chapter 15 of the
19 Dubin Report entitled "The Department of Pharmacy",
20 this is at page 194, reviews the very issue we are
21 going to be talking about, that of medication errors.
22 In that chapter it gives the various statistics you
23 heard yesterday afternoon concerning the experience
24 in non-unit dose hospitals in the United States and
25 the figures reported for medication errors.



1
2 THE COMMISSIONER: The Dubin Report
3 seems to be one thing we don't have. All right, I
4 will take your word for it. Chapter 15?

5 MR. ROLAND: I have a copy for you.

6 THE COMMISSIONER: No, I have so
7 many copies.

8 MR. ROLAND: It is just the chapter
9 so you can throw it away when you are finished.

10 THE COMMISSIONER: Yes, all right.

11 MR. ROLAND: And you will see that
12 in the introduction there is set out the very
13 percentages that we were talking about as the
14 experience for medication errors in various
15 institutions, and we will see that from the studies
16 that we filed.

17 What should be pointed out to put
18 this entire matter in perspective is that the
19 Dubin Report at page 197, refers to the fact that
20 since digoxin was made a controlled drug in March
21 of 1981 there have been, as has been noted, instances
22 of digoxin being administered to some patients to
23 whom the drug had not been prescribed, and that is
24 after March 1981. Although apparently without any
25 harmful effects.

In the reported incident it was disclosed



1
2 that in another case valium had been administered to
3 a patient rather than the prescribed drug Lasix.

4 So that when we are talking about the
5 possibility, as Dr. Spielberg has, of medication
6 errors in the various cases that we are discussing,
7 you will see that even the Dubin Report has referred,
8 and this is part of the public record, two incidents
9 of medication errors that have occurred after March
10 of 1981, including instances ---

11 THE COMMISSIONER: Where is the
12 part about after, where do I find that?

13 MR. ROLAND: Well, at the top of page
14 197, the first paragraph, I have just read that.

15 THE COMMISSIONER: All right.

16 MR. ROLAND: And of course, as you
17 know, Mr. Commissioner, that since the Dubin Report
18 the Hospital has taken significant steps to reduce
19 the possibility of medication errors by instituting
20 a unit dosage system and we will see from the
21 literature that that appears to have generally a
22 dramatic effect in reducing medication errors. All
23 of that of course occurred after March of 1981.

24 Q. Dr. Spielberg, I would like
25 to take you to Exhibit 222, that is the chapter
from the publication "Medication Errors: Causes and



1

2

Prevention".

3

A. Yes.

4

Q. And very carefully go through

5

some of the studies. Do you have a copy of the paper

6

before you?

7

A. Yes, I do, yes.

8

Q. And first of all going to

9

the Florida study we see that there is on page 10

10

of the paper a classification of the errors in that

11

study, the fourth item classified is "Unordered

12

Drug Given". I take it that would include either

13

the wrong drug given to a patient who had been

14

prescribed some drug?

15

A. Yes.

16

Q. Or giving a drug to a patient

17

who had been, who had not been prescribed any drug?

18

A. Yes, that is correct.

19

Q. We see from that paper that

20

there was an overall error rate of 18.4 per cent,

21

and if one eliminates from that the wrong time errors,

22

one gets an overall error rate of 16.6 per cent?

23

A. Yes.

24

Q. And as I understand it from

25

reading this that was a hospital in which there was

26

no unit dosage system at the time of the study?

27

28



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3

A. Yes, that is correct.

4

Q. And it was a teaching
hospital?

5

A. Yes.

6

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Q. And in particular dealing
with the Table No. 2-1 at the bottom of page 2, it
gives the total number of errors observed of 572
doses administered, and the percentage of unordered
drugs administered, and the overall errors is 18
per cent?

11

A. Yes.

12

13

14

Q. And I calculate that as a
percentage of the total number of opportunities or
drug administrations as about 3 per cent?

15

16

17

18

A. Yes, that was the upper
range that we had given yesterday.

19

20

21

22

23

24

25

Q. Yes, you gave us an upper
range of about 3 per cent and a lower range of less
than .5 per cent.

A. Yes.

Q. And then when you come to the
Arkansas study, that is a study of both a centralized
unit dose dispensing system and a non-unit dosing
system?

A. Yes.



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Q. And they gave at Table 2-2
with respect to that particular study the frequency
of errors with respect to both systems?

A. Yes.

Q. And for instance in the
unordered drug category we see an error rate of 1.7
per cent with respect to the non-unit dose system,
is that .2 per cent with respect to ---

A. 0.2 per cent after unit dose
was introduced, yes.



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Q. Yes.

A. That has been the

experience of many institutions that those particular types of errors with respect to administration of wrong drug to wrong patient in a general sense tend to decline in some cases rather dramatically with introduction of unit dose.

Q. Yes, and you gave us a figure of about a tenfold decline yesterday with the introduction of a unit dose system and I take it that in a general way is reflected by that study?

A. Yes. For example, on page 17 of this particular publication they list the overall error rates in non-unit dose again varying from 5.3 to a bit greater than 20 per cent and under unit dose systems anywhere from 6/10ths of a per cent to a maximum of about 3½ per cent. So that at least based on the literature and general experience within institutions, probably in the range of perhaps a tenfold decrease in error rate is not at all unexpected.

Q. Okay. Let's turn to the table 2-3 at page 13. It still is a table that is concerned with the Arkansas study. It is an



Spielberg, ex.
(Roland)

2382

1

2

interesting table because it seems to try and

3

quantify the reason for errors.

4

A. Yes, that is correct.

5

Q. I see for instance at Item

6

No. 9 it indicates "Never any order for this or

7

similar drug" and of the overall errors it puts that

8

at about 3.5 per cent of the overall errors?

9

A. Yes.

10

Q. At Item 16, and I will

11

get back to this when we talk about propylene glycol

12

it gives us an error, a reason for the error, a nurse

injecting IV solution too fast?

13

A. Yes.

14

Q. And No. 19 "Nurse mis-

identified patient".

15

A. Yes, correct.

16

Q. Interestingly enough at

17

24 "Nurse knowingly erred 'for patient's benefit'".

18

A. Yes, that is what is listed

19

in that category.

20

Q. Yes. Let's look at No. 2,

21

it is one of the very high percentages of errors

22

"Nurse selected and used wrong drug", and we see

23

from the footnote, that seems to indicate that many

24

of those errors involve drugs that were interchangeable,

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simply using one generic name rather than another?

A. Yes. Again, this is mostly adult patients in this particular circumstance, so, the confusions would be with various different types of antacids. Many of the confusions in fact are reasonably trivial.

Q. Yes. Before we leave the Arkansas study, I see that that involves a good number of opportunities for error. That was quite a large study. It appears at Footnote B at the bottom of page 12 that the study was based on 11,015 opportunities for error.

A. Yes.

Q. I take it that is the number of doses or administrations of the drug during the period of time of the study?

A. Yes, that is correct. Most of the studies express error rate, not per patient but rather per dose administered.

Q. If we go to the non-university hospital study with Table No. 2-4 at page 14 and again one of the error types listed is un-ordered drug. It shows a frequency of 88 errors out of a total number of drug error opportunities. I gather that again is administration of drugs?



Spielberg, ex.
(Roland)

2384

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A. Yes.

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Q. The number of drug

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administrations that occur are almost 10,000?

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A. Yes.

6

Q. That works out, we see

7

at the next table of 2-5 at about .9 per cent of
the total opportunity for error?

8

A. Yes.

9

Q. And we see as well about

10

half way down page 14 in the text that there is listed:

11

"The most common actions of nurses associated

12

with specific errors (excluding wrong time and

13

believed useful as clues to the causes of errors

14

were") and is listed there the second most common

15

specific error. "Nurse selected and used wrong
drug."

16

A. Yes.

17

Q. Is that consistent with

18

your experience as well?

19

A. Yes. There are additional -

20

the second manuscript which we provided deals

21

specifically with that issue with respect to

22

confusion of similar tablets, confusion of similar

23

vials of medication, confusion of similar names,

24

similar sizes of preparations of such.

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THE COMMISSIONER: I thought the omission to give the drug at all - maybe I have misread this table - the omission to give the drug. It starts off and one of the things, I would have thought - it makes no difference what I would have thought but it seems to me that that would be the most usual error that a nurse would make would be to forget to give it.

THE WITNESS: In most of the tables that is correct, sir, yes.

THE COMMISSIONER: Somehow or other it seems to me that:

"The most common actions of nurses associated with specific errors (excluding wrong time) and believed useful as clues to the cause of errors were:" And the don't mention that at all.

THE WITNESS: Their tables do above.

THE COMMISSIONER: Their tables do?

THE WITNESS: Yes.

THE COMMISSIONER: But when they comment on them they don't. However, that is of no particular moment.

MR. ROLAND: Q. And then the



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Kentucky study compares hospitals that do not have a unit dose dispensing system with the hospital that has a unit dose dispensing system. We see at Table 2-6 on page 16 the results of that study. In terms of the overall errors, again, I see from the total that the hospital that uses a unit dispensing system, that is, the University of Kentucky Hospital has a substantially lower error experience than those hospitals that use, or do not use a dosing system?

11

A. Yes.

12

13

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Q. And then the next study, the Ohio State Study gives again a Table 2-7 at page 17 the error percentages found in that study and for unordered drug an error rate of .47 per cent for the control system and that I gather is a non-unit dose system?

17

A. Correct.

18

19

Q. And for the unit dose system entitled Experimental System, a percentage error rate of .43?

20

21

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A. Yes. They were not quite as successful in this study at reducing errors as in some of the others.

23

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Q. Well, they seem to be



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successful in other areas?

A. In the overall rate, yes.

Q. Well, in the overall rate, but they didn't seem to reduce their unordered drug errors very much at all?

A. Yes.

Q. When you gave us a percentage for error for unordered drugs yesterday of less than 5 per cent, I take it is this study that you had in mind as the lower end?

A. As the lower end, yes, the 0.5 per cent.

Q. Yes. Now, with respect to Exhibit 223, this appears to be a paper that concerns itself with the prevention of medication errors and it is entitled specifically the indentification of one drug rather than another?

A. Yes.

Q. In basically a non-unit dose system?

A. Yes.

- - - - -



BN.jc
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Q And it gives a number of recommendations with respect to the kinds of policies that should be implemented to try to reduce errors in that kind of system, and it appears to indicate not in any statistical way but rather in a descriptive or anecdotal way the kinds of drug errors that occur in terms of drugs intended, drugs given and the consequences?

A. Yes.

Q And I take it that this is something that is consistent with your experience, that these kinds of errors occur and have occurred in the institutions that you have worked in for the kinds of reasons that are set out in this study?

A. Yes.

Q That is, a confusion of containers, whether they are vials or bottles, confusion in lettering and so on?

A. Yes, all of those apply and happen with a reasonable degree of frequency as well.

Q And the kinds of problems, I take it, that are addressed in this paper published in March of 1981 existed in the same fashion at The Hospital for Sick Children in the period that we are discussing that ended in March of 1981?



C.2

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2 A Yes, that is correct. Basically,
3 the situation was such that there were multiple vials
4 of a variety of different medications available on
5 the wards, which meant particularly that if a
6 medication was needed in a reasonably rapid fashion,
7 a vial would have to be obtained, opened, drawn up
8 and administered. Such situations where one does not
9 have reasonable control over the medication such as
10 exists in a unit dose system where there are several
11 checks and balances along the way, the pharmacist
12 drawing up the medication, the syringe being labelled
13 with the patient's name, the dose and the route, then
14 having a nurse check, and often as in the situation
15 now at The Hospital for Sick Children, two nurses
16 actually check the dose of digoxin before administration,
17 means that the entire nature of the drug delivery
18 system prior to March of 1981 and the nature of the
19 drug delivery system after March 1981 is radically
20 different, and particularly radically different
21 with respect to digoxin, particularly since digoxin
22 now not only is used under a unit dose system but is
23 considered a controlled substance, by which I mean
24 that the drug is kept under lock and key as one
25 would do, for example, with a narcotic.

So that the delivery systems and



C.3

1
2 the way in which the drug is used in clinical
3 practice has dramatically shifted in the period before
4 and the period after. Using the literature again
5 with perhaps a significant decrease in medication
6 errors with the system now in place, as indicated in
7 Mr. Justice Dubin's report; nonetheless there have
8 been patients on 4A/B receiving digoxin for whom it
9 was not prescribed after all of the measures were
10 taken, and the best possible controls placed on the
11 drug. Fortunately, none of these infants had adverse
12 effects from the drug, yet recognizing that the
13 number of errors reported is an extremely small
14 fraction of the number of errors which actually occur,
15 on page 11 of the first paper placed in evidence, it
16 is given in the range of 1 in 1,000 errors actually
17 is reported. This is probably not bad in our
18 experience, in comparing incident reports and drug
19 surveillance systems which have been instituted in
20 paediatric hospitals in a number of centres in the
21 United States which we have had the opportunity to
22 review. As such, even though the numbers would be
23 expected to be dramatically less in the pre and post
24 period, nonetheless, some children still receive no
25 accidental doses of digoxin in the post study period,
clearly, the implication being that if some of these



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infants had died, digoxin would have been found in their bodies within the period of time during which digoxin would have resided in these patients.

Q. Let me ask you about your comment that the situation is significantly different or was significantly different after March 1981 as compared to the period prior to March 1981, and set aside the unit dosage system for the moment, we know, as you have indicated, that digoxin after March of 1981 was treated as a controlled drug, it was locked up?

A. That is correct.

Q. And it required two nurses to verify a dosage before it was given?

A. Yes.

Q. Can you tell us how that would have, in your view, affected the error rate, how dramatically, if at all, that would have affected the error rate after March 1981 as compared to before March 1981?

A. Yes. Most studies done in paediatric settings, for example, in paediatric intensive care units, as well as some studies done at Johns Hopkins as well, indicate that again, the more opportunities for verifying dose and patient,



.5

1
2 for example, having two nurses examine the medication
3 as well as examine the identification on the patient,
4 would tend to decrease the likelihood of an error
5 being made.

6 Errors still are made under those
7 optimal types of circumstances. We certainly have
8 reviewed many such errors in other institutions that
9 I have been in where despite actually requiring two
10 physicians' signatures on the order, two nurses'
11 signatures for administration, there have been
12 unfortunate errors made. So that no system certainly
13 is foolproof, and yet, one would expect in a general
14 sense a dramatic reduction in error rates.

15 I should point out with respect to
16 error rates quoted for The Hospital for Sick Children,
17 which are often quoted as very low, we really do not
18 know what the numbers are because surveillance has not
19 been done. On page 196 of Mr. Dubin's report is a
20 statement from the present head of the pharmacy that
21 a minimum of 5,000 doses of drugs are administered
22 every day in the Hospital, and in the three months
23 reviewed, an average of 18 errors were reported per
24 month. This is unrealistically low or this is an
25 unrealistic number, excuse me. In fact, incident
reports really do not reflect what is going on within



C.6

1
2 the Hospital, so that we cannot use those as at all
3 accurate measures of what exists in reality. We
4 have to rely on studies where surveillance was
5 carried out and the numbers we have presented you
6 this morning.

7 Q Let us go to the Dubin Report
8 and to an incident or series of incidents that
9 occurred on the neonatal Ward 7F early in January of
10 1982 concerning epinephrine. Can you tell us about
11 that incident? I take it you were directly involved
12 with that and are familiar with that incident?

13 A Yes. The issue basically was
14 that a number of infants became acutely ill on the
15 ward at very much the same time or within a very brief
16 period of each other. No reason could be found for
17 this.

18 Initially it was thought that it might
19 be in infectious disease. An investigation was carried
20 out including by members of the Ministry of Health.
21 Dr. Evelyn Wallace was heavily involved in this, and
22 actually her studies led to the elucidation of what
23 had happened. What in fact had happened is that
24 racemic epinephrine, which is a medicine used for
25 inhalation when babies are extubated, in other words,
when an endotracheal tube that has been used for



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breathing is removed from their windpipe, it is used to help the windpipe from collapsing and getting into trouble, what had happened is that racemic epinephrine was confused for Vitamin E, Vitamin E being used in infants to prevent red cell breakdown since many premature infants are Vitamin E deficient or relatively deficient.

Vitamin E is given orally. Racemic epinephrine is only to be given by inhalation. The bottles, however, have very similar labels on them with off-green and blue stripes on them, with small lettering, and what appears to have happened is that a bottle of racemic epinephrine was mistaken for Vitamin E. But in order for this series to have occurred, not one nurse had to make an error, but in fact an entire series of nurses had to make these errors since different nurses were caring for the different infants that were involved.

One might say that the likelihood of repetitive errors when multiple nurses have actually looked at the vials would be small. I would have to agree, and yet, nonetheless, our experience has been that this tragic series of events in fact occurred despite the fact that one would say a priori that the odds of it occurring in fact are extremely small



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and the odds of it occurring are indeed extremely small, particularly if one takes into account that administration by a nurse usually involves three examinations of the medicine and the patient prior to the time that the medication is administered. If such was carried out, it meant that basically 18 oversights occurred among the six babies and nurses for that to have occurred.



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Q. Doctor, I am showing you some vials of drugs and I believe that is a set of pediatric vials.

A. Well, some of these might be used in adult medicine as well, but these were the drugs that were available and had to be used; some of them have to be diluted for pediatric use. For example, the epinephrine here is concentrated and had to be diluted with a special diluent, or normal saline. This is atropine. This one, I can't read, in honesty - hepaline, I think, Hepaléan which is a heparin solution. This one with a lot of lettering is atropine and this one is pediatric lanoxin, which is digoxin. This is pediatric strength digoxin.

MR. ROLAND: I tender that as the next exhibit.

A. As you can see, some of the labelling is small and, in some cases, the colouring on the vial is identical. So, to separate out a vial can be very difficult. In fact, we have had situations more recently in the Pharmacy and Therapeutics Committee where our anaesthesiologists have put in specific requests for different types of labelling on some of the vials because there have been problems



Spielberg
ex. (Roland)

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2 between atropine and epinephrine being filed in wrong
3 drawers. They have little drawers that are used in
4 the anaesthesia cart, and they put in a request and
5 we have helped them out in that regard, to ensure that
6 the drawers have the correct medications in them,
7 again, because picking up an ampoule, particularly
8 in a difficult situation, and trying to read those
9 where writing may not be optimal becomes extremely
difficult.

10 Q. I will show you a series of
11 vials that appear to be larger than the ones we have
12 introduced.

13 A. That is correct.

14 Q. Are those known as adult
15 size vials?

16 A. Well, again, all of these
17 medications are used in pediatrics.

18 Q. Yes.

19 A. We have here valium,
20 furosimide, which is lasix, the diuretic, and
21 adult strength digoxin. They all come in the same
22 size vials. Again, some of them might be diluted
for pediatric use; others might be administered
directly.

23 Here, we have somewhat different
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D3

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2 colours among the vials. Some are brown - that is
3 not for identification; that is because the drugs
4 are reasonably light-sensitive and will degenerate
5 in a clear vial. Others are in a clear vial, such
6 as lanoxin or digoxin.

7 Again, in reduced lighting situa-
8 tions, it is often very difficult to tell these
9 apart, and the second article deals with identification
10 of colour in vials.

11 THE COMMISSIONER: The first one
12 will be Exhibit 224, and those are all pediatric,
13 at least initially pediatric vials; is that right?
14 And the second ones are all, initially at least,
15 adult vials?

16 THE WITNESS: All of the vials
17 there might be used in children and, in fact, were
18 being used and are being used in children.

19 THE COMMISSIONER: Were they?

20 THE WITNESS: Yes.

21 THE COMMISSIONER: But these are
22 of greater strength, though, are they not?

23 THE WITNESS: Those are larger
24 vials containing 2 ml. as opposed to 1 ml., and the
25 preparations, for example, of lasix or valium, those
are the only vials we have in general of those; the



D4

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2 third being adult strength digoxin. So that is,
3 indeed, what would standardly be used in a larger
4 child - usually, we are talking larger here, probably
5 a teenager and up, or perhaps a larger child of
6 somewhat younger age.

7 The other drugs would be used
8 routinely in smaller children, the other two drugs;
9 Furosimide and valium.

10 --- EXHIBIT NO. 224: Pediatric vials.

11 --- EXHIBIT NO. 225: Adult vials.

12 MR. ROLAND: Q. Dr. Spielberg,
13 from your knowledge of the literature and from your
14 own experience in drug monitoring and surveillance
15 of various medical institutions, can you tell us
16 whether or not there are circumstances in which one
17 is more prone to make errors, drug errors, than other
18 circumstances?

19 A. It is a bit difficult to
20 get from the literature. From most of the studies,
21 in a general sense, the busier, the more urgent the
22 situation, often when staff are tired, and in fact,
23 there is good published literature, one of which I
24 believe has been introduced in testimony - a study
25 of McMaster on House Officer Performance or Resident/
Intern Performance at Night versus During the Day, any



D5

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2 circumstance where drugs have to be obtained rather
3 quickly under urgent circumstances, often with
4 reasonably tired staff and under circumstances where
5 staffing is reduced. For example, during the day
6 there are a lot of pharmacists around. There are
7 people to help out on the wards. There are people to
8 give advice about drugs. There are clinical
9 pharmacologists around. At night, very often the
10 same support facilities and staff are not available,
11 including the presence of the ward pharmacist, and
12 as such, the chance of errors being made or calculation
13 errors being missed would tend to go up, particularly
14 when other staff, who might countercheck and cross-
15 check, are not present, particularly when the situation
16 is urgent or when there are a large number of sick
17 infants around.

18 Q. What about events like,
19 for instance, Christmas? Is there anything, either
20 in your experience or the literature, that those
21 kinds of events may affect the incidence of drug
22 error?

23 A. There is nothing direct.
24 The issue, again, is that, often, staffing is short
25 at such times. House staff tend to be divided into
groups that periodically take holidays during



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Christmas and New Year. As such, there might be expected to be an increased problem in that house staff often have to work extra nights and are more tired; nursing staff is shorter. Again, under those circumstances, errors might go up.

The one thing that I left out that may be important is that the situation where errors are highest often would be expected to be the situation where the most medications are being given. For example, error rates tend to go up where you have multiple different drugs being administered to an infant. This would occur particularly in sick infants receiving multiple different medications, both orally and intravenously. It has certainly been documented in newborn intensive care units, both in terms of calculation errors made as well as incorrect administration of drugs, again resulting from the large number of potential drug exposures. So that the larger number of drugs being administered on the ward as well as the larger number of drugs being administered per patient increases the likelihood that a given patient might experience an error.

Q. Doctor, let's turn then briefly to children that were reviewed with you by Mr. Lamek.



D7

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2 Can you give us, in a very brief
3 review, your hypothesis that you have used to explain,
4 or attempt to explain, the elevation of levels in the
5 various patients that have been reviewed by Mr. Lamek?

6 Perhaps, if you want, you could
7 put them on the board.

8 A. I will try to do it in as
9 brief a fashion, just for the sake of summary, and
10 let me list some.

11 The first issue that we obviously
12 must cope with when we deal with any patient with an
13 elevated level, hypothesis No. 1, is administration
14 of drugs. We said that we cannot separate intent
15 but that we have to accept the possibility that such
16 drugs were given with malevolent intent or by
17 accident; so we have a twofold system here.

18 The second point we made is that
19 an isolated level, in the absence of timing, does not
20 allow us to necessarily calculate dose with any
21 accuracy, assuming administration, and, therefore,
22 we have multiple factors controlling our interpreta-
23 tion of how much was given.

24 As I indicated, any of the numbers
25 which we have dealt with and any of the pharmaco-
kinetic calculations that we might apply are fraught



D8

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2 with hazard. We did, however, say that some of the
3 previous discussions of huge quantities - by that I
4 mean multiple vials - is less likely than other
5 hypotheses; so, probably decreased probability with
6 multiple vials but major problems in interpreting the
7 levels in any pharmacokinetic sense beyond that.

8 The third point which I may not
9 have stated well enough was the issue with respect to
10 the drugs that were administered prior to the arrest,
11 Mr. Commissioner.

12 The issue there is that, if drugs
13 were administered and we have record of drug
14 administration close to the time of death, it suggests
15 several major issues, the first being that it pro-
16 vides an opportunity for either accident or intentional
17 administration without any other administration of
18 drugs occurring. In other words, no one had to give
19 any extra doses. The dose was ordered and that pro-
20 vides opportunity either for error having been made
21 at that time or for intent having been carried out,
22 not necessarily by the person who gave the drug but
23 perhaps by somebody who prepared the drug or, even
24 further down the line, in the overall handling of
25 the drug.

I think it is an important point



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2 because we know the drugs were given at that time
3 and, if an error were made or if the drug were
4 substituted, that provides an important opportunity
5 that we must consider. It is not the only one because,
6 obviously, drugs could have been given before or
7 drugs could have been given after at times when no
8 drug was ordered. So, the point being, drug
9 substitution, if you will - and we will use that as
10 sort of a non-heated word.

11 The second point we dealt with
12 then was artefact. What we were trying to point out
13 there were issues with respect to sampling; how
14 samples were obtained, where they were from; all of
15 the issues with respect to post mortem tissue; all
16 of the issues with respect to buried tissue and such.
17 So, post mortem events, post burial events, or post
18 preservative events and a whole series of issues
19 with respect to precisely how the tissue or the
20 blood sample was obtained in optimal or non-optimal
21 circumstances.

22 The third point, I may again not
23 have explained this adequately and, again, I believe
24 it is very important because it is an area that we
25 are learning more about and it is critical in looking,
not only at these children but children whom we have



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2 seen subsequently, and that is pathophysiology.

3 Let me very briefly again try to
4 explain what I mean by that.

5 The issue we were dealing with again
6 is the thimble and the bathtub with huge amounts of
7 digoxin in the body with very tiny changes leading to
8 disproportionate and large changes in blood levels.
9 This is something that a year ago we could not have
10 even talked about except in the hypothetical sense.
11 There was some literature; there has now been a
12 literal flood of literature in the area of how digoxin
13 levels may change in the absence of administration
14 under a variety of what we will call pathophysiologic
15 circumstances; basically, disease processes, some of
16 which we understand and some of which we don't under-
17 stand.

18 The initial published data were on
19 patients with kidney or renal disease where, despite
20 stopping the drug, the level of the digoxin, or
21 apparent level of digoxin measurable by RIA continued
22 to go up.

23 The second point then is that we
24 have seen other circumstances now, one of which has
25 been detailed in front of officials from the Province
with respect to Gary Murphy. As quite rightly stated



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2 in the testimony about Gary Murphy, it is very
3 difficult to extrapolate the information on this
4 infant any any other infant. He is unique, but I
5 would positively have to begin approaching each of
6 the other patients as at least potentially unique
7 because they are, they all might have resulted in
8 abnormalities in serum digoxin levels by processes
we understand less about.

9 If Gary Murphy died a year ago - I
10 was at his autopsy; I was there that night - my
11 primary concern would have been drug administration
12 to explain levels which, at the time, we believed
13 were in the 20s and which Mr. Cimbura recorded as
14 high as 32 nanograms per ml.
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At that time that was the only,
it appeared, reasonable explanation or most likely
explanation.

Q. Just stopping you there,
Dr. Spielberg.

A. Excuse me.

Q. There has not been put in
as an exhibit yet the report from the Centre of
Forensic Sciences concerning Gary Murphy. It is
dated May 16, 1983. I understand from Miss Cronk
that there are actually several reports concerning
Gary Murphy. The only one I have is this one. It
shows a blood digoxin level at 32.2 nanograms per
millilitre with respect to one of the samples. It
is the highest I think of the ones that was tested
at the Centre. But I think it is maybe appropriate
to tender this exhibit because Dr. Spielberg is
now referring to those very figures.

THE COMMISSIONER: Exhibit 226.

---EXHIBIT NO. 226: Report from the Centre of
Forensic Sciences re Gary Murphy
dated May 16, 1983.

MR. ROLAND: Q. Right.

A. Now, as we all had to
face the problem with Gary Murphy: the Coroner, the
Police, the Cardiologists and myself as the



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representative from Clinical Pharmacology at the time, we were faced with the situation where in fact a year before our only reasonable explanation was excessive administration. Within the previous few months even prior to this child's death there began being increasing publications on how blood levels of digoxin might go up under certain circumstances.

Further review by not myself but by outside pharmacologists, Dr. Ralph Kauffman reviewing the situation came to the conclusion that in fact administration in this infant was low on his list, whereas, most probable was a patho-physiologic state resulting from the child's heart and other organs dying in essence before the child had died and releasing digoxin.

Dr. Kauffman correctly stated that this is a hypothesis and we don't know for sure but that given all the evidence that he could adduce both for and against administration possibilities, renal failure, which in this infant did not exist, and the pathology findings in the infant, that his best explanation was indeed loss of digoxin from tissue binding.

I would agree with Dr. Kauffman's interpretation, that is the best explanation we have.



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2 But within a week of Gary Murphy's death we were
3 faced with another infant in the ICU who, despite
4 the fact that his digoxin had been discontinued, in
5 fact, the child had received only a loading dose of
6 digoxin, his serum concentrations of digoxin continued
7 to rise initially from 4.9, the next day 5.6, two
8 days later 8.

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9 Again, a year before I would have
10 had to say that something is wrong here, this child
11 must have received excessive doses of digoxin for
12 his serum digoxin levels to be rising. In light of
13 Gary Murphy and with the knowledge that this child,
14 who had a normal heart but had pertussis or whooping
15 cough and subsequently died of this disease and
16 recognizing that we had evidence during life that
17 both his kidneys and his liver were exhibiting severe
18 toxic effects, we came to the conclusion, yes, again,
19 this is abnormal pathophysiology. We don't understand
20 it, there is no evidence that this child had received
21 any additional digoxin but his serum digoxin level
22 has continued to rise.

23 THE COMMISSIONER: Who was this
24 child?

25 THE WITNESS: This child is listed
in Dr. Phillips tables.



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THE COMMISSIONER: Oh, we haven't
received it yet. Can you just give us the name, do
you know the name?

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THE WITNESS: I will have to go
back and look. I will provide that for you.

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THE COMMISSIONER: No, no, you don't
need to. We will keep an eye out for it I guess
when Dr. Phillips comes up.

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THE WITNESS: Now, Mr. Commissioner,
there have been a series of other children in whom
this has occurred in the last year, perhaps because
we are looking for it more astutely and because we
have learned a lot about digoxin in the last year.
Those are not listed in any of Dr. Phillips' reports.
My concern, if we discuss them at all, is that I
would like their names not to be introduced as such
because of the concerns about parents under these
circumstances. Digoxin didn't play a role in their
deaths. I would be perfectly happy to have other
expert witnesses review it but I don't know how you
would want to deal with that.

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THE COMMISSIONER: Is it relevant?

MR. ROLAND: Well, it is relevant

in the sense, Mr. Commissioner, it shows the phenomenon
that the Doctor is speaking to, pathophysiologic



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2 phenomenon that occurred that elevates digoxin.

3 THE COMMISSIONER: No, but other
4 drugs?

5 THE WITNESS: No, all digoxin.

6 THE COMMISSIONER: Oh, I thought
7 somebody said - didn't somebody say digoxin was not
8 concerned in the deaths of these children.

9 THE WITNESS: Digoxin did not
10 cause the death of these children but their serum
11 levels continued to rise despite no administration.
12 What we were dealing with were the levels with respect
13 to interpretation of what happened to these children.

14 MR. ROLAND: What the Doctor is
15 concerned about, and we have discussed this, is that
16 these names, he feels I think quite properly, should
17 not be released publicly because it may affect the
18 parents for no good purpose. We can identify them
19 by autopsy numbers.

20 THE WITNESS: Some are still alive.

21 MR. ROLAND: Some are still alive.
22 The Hospital is quite prepared to have any medical
23 experts of any parties, if they so wish, review the
24 charts that have the names and the identification
25 features in them in order to look at those cases
but we would prefer, unless of course, Mr. Commissioner,



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2 you require it, we would prefer the names not be
3 released.

4 THE COMMISSIONER: Well, I don't
5 require it but there is a danger once any of this
6 evidence comes in that eventually it will have to be
7 disclosed. I can't guarantee it, that's all. If it
8 is relevant, if it is on the question of digoxin and
9 digoxin increasing it sound relevant to me.

10 MR. ROLAND: Yes, I think it is
11 very relevant. It tells us things we didn't know
12 at the time of the deaths of the children we are
13 concerned with.

14 THE COMMISSIONER: Will these also
15 be in Dr. Phillips report?

16 THE WITNESS: Only if they died.

17 MR.ROLAND: Yes, not all of them,
18 some of them.

19 THE COMMISSIONER: Well, let's
20 start off with the numbers but I am afraid I can't
21 guarantee that they won't become public, the names
22 won't become public property after a while. As long
23 as you don't tell me the names, then at least I
24 can't tell anybody.

25 THE WITNESS: Okay. Again, I think
the major issue for bringing these children up is



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2 again being asked to consult on these children a
3 year ago I would have said they would have received
4 digoxin.

5 THE COMMISSIONER: Yes, all right.
6 Well, let's have the numbers then and whatever the
7 information is.

8 THE WITNESS: One child was in the
9 Intensive Care Unit with severe congenital heart
10 disease of a variety of different types.

11 THE COMMISSIONER: Can we give
12 them a number now, have we got a number or do you
13 want to just say Child 1.

14 THE WITNESS: Why don't we call
15 him Child A. Actually, why don't we call A the
16 patient I just discussed which Dr. Phillips already
17 has numbers on and will be presenting. That was the
18 child whose blood level went up from 4.9 to 8 in
19 life and post mortem was 12½.

20 THE COMMISSIONER: All right.
21 All right, Child B?

22 THE WITNESS: Child B was a little
23 child with severe congenital heart disease who was
24 in the Intensive Care Unit, who was going into renal
25 failure. Recognizing this a serum digoxin level
was obtained. Let me just put it over here.



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2 Basically we started off with therapeutic levels
3 less than 2, digoxin continued to be administered
4 for a period of time before the next level was drawn
5 and when it was recognized that the baby was beginning
6 to experience kidney problems the digoxin was
7 stopped. A day before the level of 6 was obtained,
8 two days later with no digoxin administration the
9 baby's level was 11. The baby did not show evidence
10 as such of digoxin toxicity but in fact was dying
11 of his primary disease, ended up dying. No autopsy
12 was obtained. The parents refused and the coroner
13 did not feel that this case warranted an autopsy.

14 Now, remembering that a level
15 like this ---

16 THE COMMISSIONER: What was his
17 death, what did he die of?

18 THE WITNESS: He died of his
19 severe congestive heart failure.

20 THE COMMISSIONER: Oh, yes.

21 THE WITNESS: Uncorrectable cardiac
22 disease.

23 THE COMMISSIONER: Yes, all right.

24 THE WITNESS: And, remembering
25 again that only a year before we would have considered
a level tremendously suspicious, even a level of



6 very worrisome, but also remembering that no digoxin was given between this interval and that interval in life. Again, we believed that this child fits in with one of the articles in the Annals of Internal Medicine with respect to the renal failure on digoxin levels..

This situation isn't quite as clear, but I think again is of major interest. This was a new born infant with a severe skin disease.

THE COMMISSIONER: This is Child C now?

THE WITNESS: This is Child C. This is an infant with severe skin disease which caused his skin basically to break down and die at extremely rapid rates. He was placed on digoxin because of mild congestive heart failure due to a mild cardiac disease. I believe it was both a patent ductus arteriosus and a small ventriculo septal defect.

The baby was placed on digoxin and a level came back of 3.7. The baby had normal kidney function as best as we can ascertain because, again, renal output in terms of urine flow was normal, serum creatinine remained normal throughout, which is a measure of kidney function.



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The digoxin was stopped. The next day the level went up to 4.4. Well, we said, okay, 4.4 and 3.7 aren't that different, perhaps it is just a measurement error, it was redone and it was 4.4. The trouble was that five days later the serum digoxin level was 4.4.

Now, we have said, being generous, that half lives may be of four days are reported in infants this age, so that the level should have at least come down to 2 and that is explaining on an extraordinary long half life, which is well above the mean. So, we don't have an explanation for why this baby's serum digoxin level did not come down at quite the right rate.

The only explanation we have, and again, we don't understand it fully, we certainly don't and don't pretend to, but the best explanation we have in this baby whose serum digoxin level simply did not come down despite normal renal function is that release of digoxin from damaged skin, and in fact there is a fair amount of digoxin in the skin which binds selectively to cells called Keratinocytes. That release of digoxin from skin in some way or another was confounding our blood level measurements. We don't understand quite how, but again, the



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2 hypothesis is that dead or dying tissues releasing
3 their stores of digoxin at rates which we cannot
4 predict and which we do not understand, we do not
5 pretend yet to understand, can again confound the
6 way in which digoxin is excreted and the levels that
7 we measure.

8 Now, there have been other infants
9 as well - I don't think they are particularly relevant.
10 The basic issue is that among all of these infants
11 looked at a year ago, including Gary Murphy, our
12 only explanation would have been administration and
13 now fully admitting our ignorance and our naivety
14 we are just beginning to learn about some of these
15 things with alternate explanations.

16 THE COMMISSIONER: How are we
17 going to get - perhaps I am really looking at you,
18 Mr. Roland. How are we going to get this information
19 in. I have no doubt that Dr. Spielberg correctly
20 states it but we should have something, a record
21 of these, I don't know, either the charts of the
22 children or something like that. Could they not
23 be presented in some way with the names blotted out?

24 MR. ROLAND: Well, let us consider
25 that, Mr. Commissioner. I suggested that to Dr.
26 Spielberg, to simply remove those things in the



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2 chart that would identify the patient, certainly
3 the name and address and so on. The concern from
4 Dr. Spielberg's prospective is that some of these
5 patients, I think especially Patient C by the very
6 detailed description of the symptoms and so on may
7 be identified by parents and others. So that there
8 is some problem there, but let us consider that and
9 I will speak to Mr. Lamek about it and see if there
10 is some way that there can be found to put them in.

11 THE WITNESS: Yes. No, obviously
12 I understand that you need some clarification and
13 that is obvious. My major concern again is that
14 these parents don't need that kind of grief to no
15 purpose in fact under these circumstances.

16 MS. CRONK: Could I just ask this,
17 Mr. Commissioner. Did Child C die and was there an
18 autopsy performed?

19 THE WITNESS: No.

20 MS. CRONK: The child is alive?

21 THE WITNESS: To the best of my
22 knowledge. I mean, he may have died subsequently
23 from his primary disease, I don't know.

24 THE COMMISSIONER: Well, all I
25 can say is that we get on dangerous ground when we
don't. I understand absolutely your concern for the



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parents but we get on very dangerous ground when
we try to do things behind closed doors.

THE WITNESS: I understand fully
as well.

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3 MR. ROLAND: Well, what I had
4 suggested earlier, and this was really through
5 Dr. Spielberg, Mr. Commissioner, is that any party who
6 is a medical expert and would like to see the parts
7 fully, the Hospital is certainly willing to let
8 medical experts see them, Doctor, in other words,
9 representing any parties. Now, that may not be an
10 adequate solution to the parties, but we are certainly
11 prepared to permit that.

12 THE COMMISSIONER: Yes, Mr. Lamek?

13 MR. LAMEK: Mr. Commissioner,
14 obviously this matter is going to have to be dealt
15 with at some stage, and speaking to Dr. Spielberg
16 before he gave his evidence, we discussed the
17 problem and I think he understands, he understood
18 then, that in order to make the references of any
19 help, they have (a) got to be sufficiently detailed
20 and precise so that an appreciation can be formed of
21 them, but also an opportunity has to be provided in
22 some way for verification and perhaps other assessment
23 of the material.

24 I am not sure as a first reaction to
25 Mr. Roland's proposal, although attractive, solves
the thing; I am not sure that it solves the Hospital's
legal problem to make disclosure of the files to



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3 other medical experts who are not involved in the
4 treatment of the children. But even so, that seems
5 to me to put at a disadvantage those parties here
6 who share a concern to verify and consider the
7 information but do not have available to them
8 medical experts.

9 So I see difficulties in the way. I
10 am certainly prepared to talk to Mr. Roland about it
11 and I hope we can resolve it very quickly. But it
12 may not admit an easy solution.

13 MR. ROLAND: Q. Doctor, you have
14 given us your various hypotheses applicable to the
15 children that you have been asked about by Mr. Lamek.
16 Have you completed that or are there any ---

17 A. I think these are the major
18 issues. Again, just to emphasize that this latter
19 issue is one that continues to expand, continues to
20 confuse us about patients, continues to be a major
21 matter of both clinical relevance in the use of the
22 drug as well as potential forensic relevance, and
23 just so that that point is clearly made.

24 Q. Yes, I think we have that
25 point, Dr. Spielberg.

Now, could you turn to each of the
children that you were asked about by Mr. Lamek, and



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3 if you wish to continue writing on the paper on the
4 board, you can do so.

5 A. Perhaps I can put it on the
6 board.

7 Q. Let us deal with each child
8 in turn very briefly, to summarize, how each of
9 your hypotheses apply to each of the children.

10 A. Okay, if we begin with Janice
11 Estrella, I think quite certainly we have to be
12 tremendously concerned about the second issue, the
13 issue of artefact. Scientifically, I cannot
14 accept that sample as necessarily valid. I have to
15 be concerned that it might be. Based on all that
16 has happened subsequently and our knowledge of
17 digoxin and our knowledge of tissue concentrations
18 and serum concentrations and the way in which the
19 sample was taken, I have to list artefact as very
20 high. I believe this was also the case in the CDC
21 report.

22 I must accept the possibility which I
23 think is less likely that the sample was correct.
24 I have to accept it. I have to put that issue of
25 administration down the line.

I do not have evidence that can clearly
tell me anything about pathophysiology in this infant.



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There may be issues of pathophysiology in this infant that explain her level of 72, if it is correct. I do not have evidence of it, so I cannot deal with it.

THE COMMISSIONER: I am sorry, but what is the problem about the administration? Your problem is that if ---

THE WITNESS: I have to accept it as a possibility because the level is there, but I have to scientifically believe that the level most likely is not correct.

THE COMMISSIONER: All right, okay.

THE WITNESS: And if it is not correct, then administration goes down further on the line.

THE COMMISSIONER: Well, it would help me, I thought that is what Mr. Roland was asking you, what your concerns were with respect to each of the children as to the validity of the readings; is that not what you were asking?

MR. ROLAND: That is so, and to analyze each of them in the context of the alternative hypotheses.

THE COMMISSIONER: Right, but your main concern with respect to Estrella is the artefact?



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THE WITNESS: Is the artefact, correct.

THE COMMISSIONER: And possibility
of contamination?

THE WITNESS: Exactly.

THE COMMISSIONER: Now, you have not
any particular concern, have you, with respect to
the -- or have you, with respect to the administration?

THE WITNESS: What I was trying to do,
sir, is just go through the three possibilities in
order of probability in my mind. I can try to
simplify even further.

With respect to Pacsai, my major
concern is pathophysiology, the child's primary
disease, the levels obtained and the levels that
have been obtained in other children subsequently,
and all the clinical issues that we dealt with in
this child.

With Baby Inwood, I have to here be
more concerned about administration as a major issue,
but I am further concerned about the potential of
artefact in that I really am still, albeit that it
is serum, we do know where it is from and we do
not know a lot about that sample, I still must be
concerned about the potential of artefact in that
sample.



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MR. ROLAND: Q. Just stopping you there, Dr. Spielberg, dealing with Baby Inwood, we have the level of 491 which we are told is a post-mortem serum level, and from your evidence in the last two days you have indicated to us that if that is treated as a real number, it is an extraordinarily high number for a serum level, and in fact, at the top of the alpha curve, if that was the timing of the taking of that sample, it would amount to about two and a half adult vials.

Now, can you tell us if that is the timing we fix, that is, the extreme top end of the alpha curve which would give us, then, the smallest amount or the least amount of digoxin administered during the alpha phase ---

A. Yes.

Q. --- does that amount of two and a half adult vials cause you any problems as far as Baby Inwood is concerned, for instance, with respect to any distress the baby may suffer from the volume of administration, first of all?

A. From that volume, if we say two and a half vials ---

Q. Yes.

A. --- we are talking in the



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neighbourhood -- this will be adult vials, we would be talking in the neighbourhood of 5 ml. The baby's weight, I believe, was about 2½ kilograms. This would be about 2 ml per kilogram fluid volume. Most children, even with a degree of congestive heart failure, should be able to tolerate that fluid volume.

Q. And I take it that when you talk about that kind of fluid volume at that number, you are talking about an IV push, whether it is rapid or a slow IV push, it is fluid that would be injected into Baby Inwood in a fairly short period of time within seconds or minutes?

A. Again, if we are talking about levels that high at very much the top of the curve, we are probabably talking about rather rapid administration. Precisely how fast, obviously I do not know.

Q. And I take it you come to that conclusion of rapid administration with Baby Inwood because if it was simply dripped in to the babies, it was administered through IV bag or the buretrol on a drip, the fusion rate of the liquid into the baby would not give you that kind of a number?

A. Again, with all the caveats



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we have talked about, about trying to apply kinetics in this sort of situation, my best estimation would be that it would be unlikely that we could achieve those kinds of levels by a slow infusion process.

Q. And the kinetics, I gather, tell us as best they can that if it was a slow infusion process, the graph would be something more like an oral administration rather than an IV push administration?

A. Yes, depending on rate again. Again, I do not want to make a big story about kinetics in that I think it is very difficult to apply under these circumstances. But we would expect a slower, more gradual rise rather than an acute jump to a number as high as 491 from a continuous infusion as opposed to an IV bolus.

So to that extent, we can think of it more like this gradual rise which occurs from oral administration, but it may not be at all exactly to say, but certainly the peaks would be expected to be lower.

Q. And you told us the other day if it is an IV push mode of administration, that that has inherent in it a problem with respect to propylene glycol?



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A. Yes.

Q. Can you tell us, because I gather you indicated yesterday that you were looking up specifically information about the toxicity of propylene glycol when administered as in an IV push, can you tell us what information you found with respect to that subject matter?

A. Yes, in the first place, this is not new. I have known this since medical school. In fact, the classic studies on propylene glycol toxicity date from 1966.

The issue was that, not with digoxin in this situation but the drug was Dilantin, an anti-convulscent, which is suspended in the same concentration of propylene glycol that digoxin is in, 40 per cent propylene glycol. Now, it was noted by cardiologists when they were trying to use Dilantin in situations to treat arrhythmias, which is one of the other indications for the drug, that if they administered the drug too rapidly intravenously over a matter of, say, one to three minutes, the patients would suddenly begin developing a variety of toxicities. The first thing noted was fall in blood pressure. Some patients would begin developing a variety of cardiac arrhythmias,



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2 cardiac slowing or bradycardia was the first thing
3 which occurred, varying degrees of atrial ventricular
4 or AV block which occur, leading to complete
5 dissociation of atrium and ventricular rates and
6 also the possibility of development of a variety of
7 ventricular arrhythmias, depending on the patient
8 and depending on the disease that the patient had.

9 In general, the toxicity was worse if
10 the patients were reasonably hypoxic or particularly
11 ill or had congestive heart failure.

12 Now, this was originally thought to
13 be due to Dilantin, and the classic studies were
14 done, separating the Dilantin, the vehicle in which
15 the Dilantin is suspended and propylene glycol itself.
16 These were animal experiments, and it was demonstrated
17 that in fact all of the effects of the rapid
18 administration of Dilantin were attributed not to
19 Dilantin, in fact, but rather to the vehicle itself,
20 to the propylene glycol which was present in it.

21 What kind of amounts and what kind of
22 concentrations are we talking about? Here, again,
23 we have to go back to the human literature, and
24 again, it is mostly adults with either Valium or
25 Dilantin. The amounts that we are talking about are
as small as 1 to 2 to 3 millilitres in an adult



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3 pushed rapidly. By rapidly I mean administration
4 over a course of a minute to two minutes. So that
5 our current recommendations, for example, in using
6 a drug like Valium as an anti-convulscent acutely
7 or Dilantin either for heart disease or seizures
8 is that the drug be pushed in very slowly over a
9 period of five minutes perhaps, if we possibly can.

10 THE COMMISSIONER: Is this the
11 same for digoxin?

12 THE WITNESS: This is the same for
13 digoxin.

14 THE COMMISSIONER: Well, was digoxin --
15 you were talking about your current recommendations.

16 THE WITNESS: Yes.

17 THE COMMISSIONER: How long is
18 current? Is this in the past five years; would this
19 cover our period?

20 THE WITNESS: This would cover
21 10 years.

22 THE COMMISSIONER: Well then, I take
23 it, that digoxin to be administered in whatever
24 manner, to be administered is to take into considera-
25 tion ---

THE WITNESS: Oh yes, and in fact,
the standard way that we would administer it, if we



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3 knew we were administering digoxin and had the
4 intent of administering digoxin, is that we would
5 not give it as a very rapid push directly into the
6 lower part of the IV line. It might be put into
7 the intravenous line, then it would be administered
8 as the IV fluid carried it in over a slower period
9 of time.

10 THE COMMISSIONER: What you said
11 yesterday was that it would be an unauthorized
12 administration of digoxin that would result in this
13 problem from this other drug, propylene glycol?

14 THE WITNESS: Yes, that is correct.
15 So in other words, if somebody were intending to
16 give digoxin by the proper way ---

17 THE COMMISSIONER: Yes, by the
18 proper way, there would be no problem?

19 THE WITNESS: They would give it
20 very slowly. If they were intending to give a
21 larger volume, when we are talking about overdose
22 kinds of situations, if they intended to give a
23 larger volume intravenously either by a rapid push,
24 certainly one would expect some effects of the
25 propylene glycol, particularly in these children.



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The volumes then get rather large, because for example if they administered 500 milligrams, one adult vial, that is 2 cc's in a child now weighing perhaps 4 kilograms, as opposed to 2 cc's in an adult. So even if that went in a little bit slower one might well be concerned about propylene glycol toxicity. If it was mistaken for a drug that we normally give by rapid push, such as lasix, which is usually given as a rapid bolus, again even if we were talking about smaller total amounts the possibility again exists that the propylene glycol might cause acute toxicity in the child.

THE COMMISSIONER: Yes, well, I can understand that, if it happens, because it is part of the digoxin and it is - let us say for an example it is an intentional overdose or really is - I know it might be a matter of scientific interest, but it is hardly of any general interest, which killed the child --

THE WITNESS: No, it is a major issue in terms of timing, sir, because the propylene glycol is going to act very much more rapidly potentially than the digoxin itself and that I think is the point. Certainly with respect to intent or anything else if somebody is giving intentionally a drug and the



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2 vehicle ends up causing the problem, there is no
3 difference of course, but in terms of timing it may
4 be an important issue.

5 Q I gather Dr. Spielberg, that is
6 the significance with respect to propylene glycol
7 in the cases that you have analyzed and we will get
8 to them in more detail, but that it has a very rapid
effect.

9 A Yes.

10 Q Especially compared to digoxin?

11 A Yes, the onset within matters
12 of seconds to minutes after a rapid push.

13 Q Yes.

14 A It can be modified by all kinds
15 of things; for example, atropine administered at the
16 same time can partially block the effects, but not
17 entirely, because the effects appear to be to that
18 extent not dissimilar to digoxin, in that the effects
19 are mediated both by the vagus nerve as well as by
direct effects of the drug on the myocardium.

20 Q And getting back to Baby Inwood
21 with the figure of 491, if that is treated as a real
22 figure during, for instance, the alpha curve phase,
23 then it is likely that that I take it, or more likely
24 that that drug was, that digoxin was injected by an
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IV push, whether it is rapid or slow, rather than
being dripped in at a slow rate of infusion?

A. Certainly compared to a drip,
yes.

Q. And those are the two alternatives,
I gather?

A. Yes.

Q. Either an IV push or the drug
being placed in the IV bag or in the bolus and
dripped through.

A. Again I would have to put the
caveat on it that because of the tremendously
variable and different kinetics that we are talking
about I wouldn't in any way want to state, you know,
precisely how the drug was administered, at what rate
or whatever, I think we have to be very careful.

THE COMMISSIONER: Speaking about an
IV push.

THE WITNESS: Yes.

THE COMMISSIONER: Do you mean with the
syringe into the veins or something?

THE WITNESS: Well, there are several
ways to do it.

THE COMMISSIONER: But if the child
is being fed intravenously.



G.4

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THE WITNESS: Right.

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THE COMMISSIONER: With the usual system.

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THE WITNESS: Right.

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THE COMMISSIONER: There is no way
you could inject it into that system that we would
call an IV push?

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THE WITNESS: Oh, yes. Well, there
are several places you can put the drug in an IV
system. You can put it in a bottle, you can put it
in the buretrol and most IV lines have injection
ports in them low down to the baby.

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THE COMMISSIONER: What point does it
become a push?

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THE WITNESS: Usually when we are
talking about putting it close to the baby, okay.
There are different IV lines in terms of how much
volume exists from that push site to the baby.

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THE COMMISSIONER: I am assuming that
someone pushed this digoxin, let's talk about digoxin
for a moment.

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THE WITNESS: Surely.

THE COMMISSIONER: And obviously some
digoxin appears to have got in, some considerable
amount, pushed it in low down in the system.

THE WITNESS: Right.



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THE COMMISSIONER: And would get in?

THE WITNESS: Right.

THE COMMISSIONER: All you are really saying is while there is this enormous amount of digoxin in the baby it is very early in the alpha treatment, and the baby conceivably could have died of the other drug, the propylene glycol?

THE WITNESS: Yes.

THE COMMISSIONER: Is that what you are telling me?

THE WITNESS: That is basically it.

THE COMMISSIONER: With a line-up of suspects I suppose as to who was around when and where, it would simply mean that the injection took place closer to death perhaps than we would have thought?

THE WITNESS: I think it would give two arguments as we were trying to discuss with Mr. Lamek yesterday in terms of, you know, how long; the higher the level the less volume of distribution, the closer you are to the time of administration. If we add propylene glycol into this extraordinarily high level, the likelihood is that death would have been extremely close after administration, within seconds to minutes. Again we can't argue that 100 per cent but I think it is reasonable if that 491 is correct.



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THE COMMISSIONER: Whenever you like,
Mr. Roland.

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MR. ROLAND: I have one other question
just before we leave this subject.

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Q You told us that propylene glycol
is used as the medium for digoxin, that digoxin
dissolves in it?

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A. Yes.

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Q Is digoxin water dissolvable,
water soluble?

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A. It is what we would term
sparingly soluble in water, which means if you try to
dissolve it in water some will go in but not
pharmacologically adequate amounts.

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In other words, in order to produce
a pharmaceutical preparation to maintain the digoxin
in solution you require a pH adjustment in there; you
require the propylene glycol as well as alcohol to
maintain it in suspension.

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Now if you, for example, tried to
suspend some digoxin in water, some digoxin would be
suspended. A lot of it would precipitate out, and
if you kept the solution around most of it would
precipitate out.

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MR. ROLAND: Thank you.



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THE COMMISSIONER: All right, we will
take 20 minutes then.

--- Short recess

--- Upon resuming:

THE COMMISSIONER: Yes, Mr. Roland?

MR. ROLAND: Thank you, Mr. Commissioner.

Q. Dr. Spielberg, we were dealing
with Kristin Inwood, and you have told us about your
artefactual concerns?

A. Yes.

Q. Do you have any other concerns
about Kristin Inwood, and in particular in reference
to your various hypotheses?

A. Yes. There are several other
things I suppose that we should list with respect to
this latter issue of tissue damage and such, and that
is that the baby did indeed have areas of cardiac
necrosis.

Now that included some sub-endocardial
damage which means in the muscle directly adjacent
to the chamber of the heart where the blood is; as
well as the papillary muscle which sits out within
the chamber. So that we have to add into this
question myocardial damage. We know that the myo-
cardial damage occurred, and we said there is



G.8

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2 tremendous quantities of digoxin within the heart
3 muscle itself and again some contribution towards
4 that level may have been made by damaged muscle.
5 Recognizing again that muscle can be three-hundredfold
6 greater concentration on a unit weight or volume basis
7 than the amount in serum.

8 So with this child in terms of
9 questions with respect to the level, we do have to be
10 concerned about the nature of the sample and how it
11 was handled, et cetera, in storage. We also have to
12 add in one additional caveat, that being in this
13 particular situation the myocardial damage which was
14 evidenced at autopsy.

15 So these will be the basic concerns I
16 think that we have already gone through with respect
17 to interpreting this particular level and the
18 pharmacokinetic issues which you mentioned a moment ago.

19 Q. In terms of ---

20 A. I am sorry, we do have to add
21 one other thing in terms of artefacts.

22 Q. Yes.

23 A. That being a calcium of 34.

24 Q. Yes.

25 A. Again, Mr. Commissioner, I don't
know what to make of that. It was probably



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administered calcium during the resuscitation, but I don't know what effect that nearly, actually it is about three-and-a-half-fold increased calcium might do, for example, on release of digoxin from myocardium, either during the agonal events, the resuscitation, or post mortem, so we do have to at least add that in because we don't have a good idea what that might do. Certainly calcium can have marked effects on membranes and such and we have to add that in as an additional caution on the infant.

Q. Let me ask you with respect to Kristin Inwood about your administration hypothesis?

A. Yes.

Q. And you have told us that intent of course is always one possibility. With respect to error, we have been taken by you in your earlier evidence to the progress notes on the chart of Kristin Inwood, and we have it I gather from page 63 that lasix was given by IV, by a resident, some time between 2 a.m. and the time of the Code 25 at 2:30?

A. Yes.

Q. Does that play on your concern with respect to error?

A. If in fact we are dealing with administration and the level in serum reflects a high



G.10

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2 concentration, given again that we have just shown
3 that the vials of injectable lasix and the vials of
4 adult strength injectable digoxin are extremely
5 similar; if an error had been made with digoxin in
6 error substituted for the last dose of lasix which
7 the child received before her arrest, then in fact
8 this would have been a reasonable place where such
9 an error would have occurred. Vials of similar size;
10 a drug that had not been previously ordered, this
11 was ordered because the child was getting acutely ill
12 at that time and it had been drawn up therefore
13 reasonably quickly after the resident had arrived
14 on the ward, and as such that is not an unreasonable
15 place for an error to have been made. Similar vials,
16 reasonably urgent situation, and again substituting
17 that for the lasix and given in the mode in which
18 lasix is normally administered, which is very rapidly
19 IV push, could well have accounted for both the
20 extremely high blood level. The potential of lack
21 of distribution in this infant, which we have to
22 postulate to expect the extremely high blood level
23 and her subsequent course.

24 Q. And I take it in that context
25 you would be concerned with toxicity from propylene
glycol being the medium in which digoxin is found,



G.11

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2 being administered instead of lasix?

3 A. Yes. If 2 cc's, let us say for
4 example, and again we don't know how the drug was
5 being diluted and there are multiple steps from
6 drawing up the medication to administration, we don't
7 know precisely how they were being handled; the
8 nature of the syringes; the movement of the drugs
9 around the ward, because this was not a controlled
10 drug situation at all on the ward at that time.
11 Then if a significant volume, and perhaps even a
12 small volume of the digoxin were given, it might well
13 have had those kinds of effects.

14 Then one has to deal with the level
15 of the digoxin and whether the level of digoxin could
16 conceivably have been achieved by the various
17 mechanisms that we are talking about, taking into
18 account that the sample presumably must have some
19 artefacts in it if nothing else from storage from
20 that period of time. Some concentration perhaps in
21 volume and such. We don't know what happened to it
22 in Virology before it reached the freezer, et cetera.
23 Because of all of those issues it becomes very
24 difficult to say anything in a hard pharmacologic or
25 pharmacokinetic sense. I think we would be a bit
foolish to try to go beyond that point. Except that



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is a very reasonable time for such an event as you suggest in terms of an error to have occurred with the consequences that resulted clinically.

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Q. Can we go to the next baby then, Baby Miller.

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A. Oh, I probably had better erase this. The next baby is Allana Miller.

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Now again we have the issue of administration here, cautioning that probably the only patient in the entire series for whom we have very excellent evidence of administration is Baby Cook. Simply because in fact the levels were found during resuscitation and post mortem, and we have very good evidence that the baby was not on digoxin prior to the time that these levels were obtained. So certainly in Baby Cook we have very good evidence for administration.

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In Baby Miller we have somewhat less good evidence for that, in that we only have a post-mortem value.

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What concerns do we have with respect to the postmortem value and what it might mean?

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The two questions we basically have is what was her primary disease; what led to the child's fever, high white count, low platelet count, bloody



G.13

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2 stools, because we don't know that we can't really
3 comment on whether that could have an influence on
4 the pathophysiology of the process, we just don't
5 know. It might, and we have to take that as at
6 least one possible concern, albeit that we can never
7 really ascertain that. Again, in light of subsequent
8 events one has to be cautious and say with some
9 caveat perhaps the disease played a role, we have
no evidence for this.

10 The second thing is the issue of
11 resuscitation trauma. Compared to most of the other
12 infants in the series, in fact compared to all of
13 them, there was evidence at autopsy of a larger amount
14 of damage as a result of the resuscitation process.
15 This again though nobody's fault, simply from the fact
16 that needles have to be injected through the cardiac
17 muscle and by, in this child, going all the way to
18 putting in a pacemaker which requires insertion of
19 wires into the heart. So there was a good deal of
20 blood both in the sac around the heart, the pericardium,
21 as well as substantial amounts of blood in both sides
of the remainder of the chest, and the right and
left halves of the chest.

22 How could this affect things? Again
23 during the process we are not sure where the blood
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G.14

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2 sample was taken from. If it was taken intra cardiac
3 this might have a rather large effect. If, however,
4 it was taken from another site, such as a vein or
5 whatever, it still might have a significant effect
6 again because of damage to the cardiac muscle
7 releasing some digoxin.

8 This obviously does not happen in every
9 baby that is resuscitated. None of the events we
10 are talking about happen in every baby. We are
11 talking about unusual events certainly can occur in
12 a specific infant.

13 Then we have to deal with admini-
14 stration. Again, we expressed one possibility, that
15 being a dose of drug given within five minutes of the
16 child's asystolic episode, a very short interval
17 from the administration of lasix to the arrest of the
18 child. That is one opportunity during which either
19 error or an intentional substitution of drug could
20 have occurred. Again remembering that when somebody
21 asks for a drug to be administered, a physician, the
22 drug is drawn up and he is handed a syringe containing
23 a liquid, trusting in fact that it is the compound
24 that he wishes to give, or that he has asked for.
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So, that is one possibility at that time; on the other hand, both pharmacokinetically and clinically it could have occurred before or it conceivably could have occurred even after, during the resuscitation process.

THE COMMISSIONER: Does the doctor, does he not check the drug when it is handed to him, is he not supposed to?

THE WITNESS: It varies during urgent situations from yes to no.

THE COMMISSIONER: Well, what is the merits in having the doctor dispense the drug if he doesn't check it?

THE WITNESS: I think that is a valid question indeed.

THE COMMISSIONER: Is there much of a trick to it?

THE WITNESS: The rules should be that somebody opens a vial, draws up, shows the vial to the doctor, shows the syringe to the doctor and injects it. Particularly during urgent circumstances that does break down. I have certainly seen it happen and it happens not infrequently.

THE COMMISSIONER: Oh, I am sure it breaks down but the responsibility is the doctor's,



Spielberg, ex.
(Roland)

not the nurse's. Am I not correct on that?

THE WITNESS: In terms of ultimate administration the person who gives it must accept responsibility for it, as well as everybody else involved in the preparation all up and down the line. In fact, in modern hospital circumstances we are dealing with much shared responsibility. In unit dose we have pharmacists making up the drug, sending it to the floor, nurses checking it and if it is a drug that must be administered by the physician, physician administration.

THE COMMISSIONER: Yes. All right, carry on, please.

THE WITNESS: Okay. So, those are the reasonable possibilities we have for Baby Miller. For Baby Cook I can really only accept one possibility, that is, the child received a dose of digoxin. We can talk about the artefacts, we can talk about substance X I believe it's been called in these hearings, et cetera. The only reasonable possibility that I can come up with, perhaps someone can come up with something else, is administration. Again, we are left at bifurcation of administration into error or intent or malevolent intent. Beyond that, I don't think we can say very much. We have



1
2 gone through some of the kinetics. I think we have
3 taken them as far as they can be taken because we
4 simply lack adequate data to fill in all the multiple
5 gaps about whether 1100 might have gone up or come
6 down or 73 gone up or come down. We are guessing
7 much beyond that point and we can only provide
8 minima and maxima in terms of amounts.

3 8 The only way we can separate out
9 the issue of clear malevolence would be many vials
10 of digoxin having been given to the child. I
11 believe that pharmacologically and practically that
12 is unlikely and that we are probably dealing with
13 a single vial, presumably a single adult vial which
14 then still leaves us with the predicament that we
15 are all facing, how did the drug get to the baby,
16 was it in error, was it intentional and that
17 pharmacologically I can't offer anything about.
18 All I can do is suggest times and possibilities.

18 In fact, with respect to times
19 we have multiple drugs being given intravenously
20 prior to the child's final arrest and 20 some odd
21 drugs being given during the arrest, some of which
22 might have accounted for the levels including the
23 tissue levels which we see.

23 MR. ROLAND: In terms of IV pushes, you have
24
25



1
4 2 told us about the real risk if it is a rapid IV
3 push?

4 A. Yes.

5 Q. That the baby will die of
6 the administration, rapid administration of
7 propylene glycol rather than from the dig. itself
8 and that will occur very rapidly?

8 A. Yes.

9 Q. Now, as I understand your
10 evidence, you define a rapid IV push as something
11 that would take around five minutes?

12 A. Most of the literature
13 suggests a little bit more rapidly. Most of the
14 literature for example on Dilantin or on Valium would
15 suggest a minute to perhaps three minutes, but
16 obviously there is a range and it is going to depend
17 on the volume given to the baby as well as the
18 rapidity.

18 Q. Well, let's talk about an
19 adult vial of digoxin. How long would you estimate
20 it would take to rapidly push that amount of digoxin
21 and propylene glycol through an IV into a baby's
22 system?

22 A. It could be done in a very
23 short period of time.
24
25



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2 Q. What is the shortest period
3 it could be done?

4 A. I can't give you a real
5 number in seconds. Certainly in less than a minute,
6 probably in less than half a minute and again it is
7 going to be dependent on what size needle is in the
8 vein, because if too much pressure is applied the
9 vein will infiltrate, the needle will infiltrate,
10 which means basically the needle comes out of the
11 vein and you don't get adequate profusion, and on the
12 size of the needle, on the size of the needle that
13 you have on the syringe that you enter the port on
14 the IV site and the size of the syringe as well
15 because different size syringes tend to deliver drug
16 under different pressure.

17 But certainly one could well imagine
18 that 2 ml could readily be administered in a very
19 brief period of time, assuming most standard 23 gauge
20 needles, IV needles.

21 THE COMMISSIONER: I have forgotten
22 what an adult dose is.

23 THE WITNESS: It is 2 millilitres
24 containing 500 micrograms or a half milligram
25 of digoxin.

MR. ROLAND: Q. Okay, you have told



1
2 us how long it can be done, physically how long it
3 can be done and you said it can be done in a very
4 short period of time. How long would it have to take
5 to avoid having a toxic effect due to the
6 propylene glycol?

7 A. Now, again, we don't have
8 good data on what 2 millilitres would be like in a
9 small baby. Most of the data again are 1 to 2
10 millilitres in an adult or a larger infant and Valium
11 used in a smaller infant. Usually we would aim
12 at perhaps five minutes.

13 Q. Are you saying that any-
14 thing under five minutes you run the very real risk that
15 there will be toxicity from the propylene glycol
16 for that quantity?

17 A. Again in a volume dependent
18 sense, as you suggest, yes. If for example one gave
19 a therapeutic dose of digoxin to the infant.

20 Q. Yes.

21 A. Then the total volume is
22 really exceedingly small. We are often dealing with
23 .1, .2 millilitres, extremely small volumes. Under
24 those circumstances the propylene glycol issue
25 becomes less and less important. When we are getting
up to 2 millilitres there is indeed a significant



1
2 risk.

3 Q. Yes. And you have told
4 us that it is in that 2 millilitre range for many
5 of these babies that is found your best estimate
6 for the amount of digoxin that was likely administered
7 to them to arrive at the numbers in the alpha phase
8 that we see with respect to these babies?

9 A. Yes. It is a consistent
10 amount. We can't say certainly with any degree of
11 certainty whether it might have been a little bit
12 less or it might have been a little bit more again
13 because not knowing time we are foolhardy to try to
14 do that.

15 That amount of digoxin, however,
16 would account or could account, again depending on
17 the timing in kinetics for any of the levels
18 which we have seen.

19 Q. Yes, all right. You have
20 told us that digoxin ---

21 THE COMMISSIONER: I am sorry, I
22 keep forgetting because I am having trouble with it.
23 I have no trouble with doses, paediatric doses, one
24 is 10 times the other?

25 THE WITNESS: That is correct.

THE COMMISSIONER: But the



1
2 concentrations, what is the paediatric dose again?

3 THE WITNESS: A paediatric vial
4 is 50 micrograms.

5 THE COMMISSIONER: 50 micrograms.

6 THE WITNESS: In 1 millilitre.

7 MR. ROLAND: Q. Doctor, that
8 is micrograms of digoxin, is that correct?

9 A. Yes.

10 Q. Yes.

11 A. Micrograms of digoxin.

12 The adult vial contains 500 micrograms in 2 millilitres.
13 So, it has more per millilitre but it also has a
14 larger volume as well. It will be 250 micrograms
15 per millilitre.

16 THE COMMISSIONER: Yes. Well,
17 the concentration then is not 10 to 1?

18 THE WITNESS: No. The total amount
19 is 10 to 1, the concentration is approximately 5 to
20 1.

21 THE COMMISSIONER: 5 to 1.

22 THE WITNESS: That's correct.

23 MR. ROLAND: Q. Doctor, you have
24 told us that ---

25 THE COMMISSIONER: I am sorry, I am
going to interrupt once more. You also said that you



1
2 are reviewing this and you have done this to us
3 before, you were saying that while it is obviously
4 not the maximum nor for that matter the minimum
5 that one adult vial could account in each one of
6 these four children, that the administration could
account for their readings?

7 THE WITNESS: Yes.

8 MR. ROLAND: Q. Doctor, as I
9 understand your evidence, carrying that a little
10 further, that that is your most reasonable hypothesis
11 as far as you are concerned, that to take it into
12 the beta phase or the steady state phase would require
13 too many vials of digoxin, too great a volume of
14 digoxin and propylene glycol. and to go back to
15 the acute phase, really, although it is a much
16 smaller amount of digoxin, is such a short time
interval that it probably isn't realistic for most
17 or all of these babies?

18 A. Yes.

19 THE COMMISSIONER: What isn't
20 realistic?

21 MR. ROLAND: The time interval that
22 it is in the acute phase, that is, to get the numbers
23 we've seen would require the sampling to be taken
almost at the same time as the administration.
24
25



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2 THE WITNESS: Or that circulation
3 has ceased.

4 Q. Yes.

5 A. The two issues will be -
6 on the top side certainly we are dealing with un-
7 realistic both physical handling of the drug,
8 unrealistic volumes, unrealistic manners of
9 administering those kinds of volumes and the problem
10 of simple fluid overload as well as potentially
11 propylene glycol toxicity just from those huge
12 quantities that were talked about.

13 On the down side issue, that still
14 remains a possibility.

15 Q. Yes.

16 A. For babies other than Baby
17 Cook because we already know that there are significant
18 amounts in his tissues. So, we have to say that some
19 drug certainly has distributed into his tissues.

20 Q. Yes.

21 A. For the other babies ---

22 Q. So, you would put Cook more
23 likely, even more so than the other babies in the
24 beta phase, in the distribution phase?

25 A. In the alpha phase.

Q. In the alpha phase?



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A. Yes.

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Q. I am sorry.

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A. Coming down that alpha
phase of distribution.

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Q. I see.

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A. The other babies ---

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THE COMMISSIONER: There has been
some distribution.

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THE WITNESS: There had to be some
distribution.

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THE COMMISSIONER: Yes.

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THE WITNESS: In the other babies
it is conceivable the drug could have been given
very close to the cessation of circulation.

13

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Q. Yes.

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A. Or even inter-resuscitation.

16

Under which circumstances in fact it wouldn't have
distributed at all even out of serum.

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Q. I see.

18

A. And then we are talking

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about very small amounts far back. The issue being,
again, if I can try to clarify, that we have to
consider that the mechanisms may be different among
different babies. They may in fact be a uniform
pattern but what happened may in fact be different

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2 among some of them. Some may not have received any-
3 thing and be exhibiting pathophysiologic phenomena.
4 Others may in fact have received inadvertent doses
5 and others may have received intentional doses.
6 Any of those combinations are possible throughout the
7 whole series, as well as the possibility that the
8 exact amounts given might vary considerably.

9 Q. I see.

10 THE COMMISSIONER: Doctor, I want
11 to stop you again. With Cook, you say Cook had to
12 be in the beta phase, or at least had to be well into
13 the alpha phase, had to be some distribution?

14 THE WITNESS: Somewhere along that
15 alpha phase, yes.

16 THE COMMISSIONER: And it could have
17 been the beta phase too, could it not?

18 THE WITNESS: Well, again, then
19 we would have had to assume the multiple vial theory
20 for if it had distributed fully to get 70 range then
21 we are talking about multiple vials again. It is
22 still possible of course.

23 MR. ROLAND: Q. Isn't the problem
24 you have with the beta phase, as the Commissioner
25 puts it to you, that as I understand your evidence
that that would require a tremendous volume of the



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drug?

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A. Yes.

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Q. And likely the baby would

5

drown of that volume of administration before the

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baby ever reached the beta phase?

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A. We are talking about

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substantial volumes, substantial technical difficulties

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of doing it, all of which make it unlikely. One

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certainly cannot absolutely rule it out, but again,

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I think it makes it so unlikely that looking at both

12

the clinical status of the babies, what reasonably

13

goes on in the care of infants and what kinds of

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concentrations we are talking about, much less than

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multiple vials makes much better sense. In fact, a

16

single vial makes better sense whether one is

talking about malevolent or accident administration.

17

Q. And I gather, Dr.

18

Spielberg, that the other comment you make about

19

Baby Cook is that it is likely the baby would have

20

survived to steady state, to the beta phase, if given

multiple vials?

21

A. I think it would be very

22

unlikely under those circumstances, particularly in

23

Baby Cook's circumstance, because, remember, this

24

child had heart disease that presumably would have

25



1
2 been made worse by digoxin accumulation.

14 3 Q. Exactly. There is the
4 drowning issue and then there is the heart disease?

5 A. Exactly.

6 Q. And both of those would
7 likely have prevented Baby Cook from surviving to
8 get to the beta phase, if we are operating on a
multi-vial theory, yes.

9 A. One would have expected him
10 to be more susceptible.

11 Q. Yes.

12 A. In fact, based on his
13 heart disease than the average child.

14 Q. Yes.

15 A. Considerably more so in
16 that his form of congenital heart disease is in a
17 sense a potential contra indication to using
digoxin.

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Q. Now, one last question. You have told us that the administration of digoxin traditionally when administered in an IV mode is put into either the buretrol and dripped through or into the IV bag and dripped through, and that is the traditional and accepted way of administering an IV medication of digoxin.

A. It also can be put in the line, but again, very, very slowly.

Q. Very slowly, and you have told us that that should be at least five minutes?

A. At least.

THE COMMISSIONER: How do you put it in slowly? Do you mean put a little at a time, is that the idea?

THE WITNESS: Yes, a little at a time with a very slow running IV rate, so that the drug is not rapidly washed into the infant. It goes in rather over a slow period of time. Typically, you would want to put it, if possibly not close down but use an IV port higher up. The volume of the line itself is about 10 cc's, and that takes a long time to get in.

MR. ROLAND: Q. And I gather to simply put it in the buretrol or put it into the



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2 IV bag can be done fairly quickly? You simply
3 inject it and that takes a matter of seconds?

4 A. Yes, typically one would not
5 choose the bag in that again these babies are
6 usually receiving rather slow IV rates, reasonably
7 small volumes, and the buretrol is used in a way
8 to regulate the amount of fluid that would be given
9 per unit time. The bag may contain 250 cc's, but
10 that may go in over a matter of a very long period
11 of time or greater than a day, and the bag would
12 have to be changed. Usually what would happen is
13 that an amount would be put in the buretrol that
14 would run in over a reasonable period of time.

15 MR. ROLAND: Thank you, Dr. Spielberg.
16 Those are all my questions.

17 THE COMMISSIONER: Thank you.
18 Mr. Ortved, is this your client?

19 MR. ORTVED: No, he is not.

20 THE COMMISSIONER: Mr. Brown?

21 MR. BROWN: I have no questions,
22 Mr. Commissioner.

23 THE COMMISSIONER: Mr. Strathy?

24 CROSS-EXAMINATION BY MR. STRATHY:

25 Q. Doctor, I was not here on
Monday when Mr. Lamek took you through your



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qualifications, but I gather from your evidence that
you are an M.D.?

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A. That is correct.

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Q. And you received that at

6

Johns Hopkins University?

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A. No.

8

Q. Excuse me, you had better

take me back, then. Where did you get your M.D.?

9

A. I have an M.D. and a Ph.D.

10

in Pharmacology from the University of Chicago.

11

Q. So your Ph.D., then, is in

12

Pharmacology?

13

A. In Pharmacology, correct.

14

Q. But I am right that you did

attend Johns Hopkins University?

15

A. I was on the faculty in

16

Pharmacology and Pediatrics at Johns Hopkins.

17

Q. And I am told the Johns

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Hopkins is recognized really around the world as

19

one of the leading pediatric hospitals?

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A. We felt it was a good

institution, yes.

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Q. It certainly ranks on a level

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with the Hospital for Sick Children?

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A. It is much smaller, as a result

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much less complex. The types of patients seen are reasonably reflective but on much smaller numbers than one sees at the Hospital for Sick Children.

Q. But certainly in terms of its reputation, it is at the same sort of level as Sick Children's?

A. Yes.

Q. Doctor, I take it from your evidence that you consider yourself to be a scientist; am I correct in that?

A. My primary emphasis I probably spend about 70 per cent of my time doing basic science research related to human drug toxicity.

Q. And in fact, you are tied, if you will, to the research part of the Sick Children's Hospital?

A. Yes, I have an appointment within the Research Institute.

Q. So it would be fair for one to describe you as a scientist?

A. If you wish to use that term, certainly.

Q. Well, let us be specific. As I understand the methodology that you have applied



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2 here, it would be accurate to describe it as a
3 scientific methodology in the sense that you have
4 examined some data and tested various hypotheses
5 to eventually come up with a hypothesis or perhaps
6 several hypotheses that you regard as reasonable in
7 the circumstances?

8 A. Yes, I think that is a fair
9 statement.

10 Q. And is that not the sort of
11 methodology a scientist applies when he examines
12 data?

13 A. Yes, we hope that we can
14 train our clinicians to do similar kinds of things
15 in clinical settings, and the two often go together.
16 But the basic method is that of scientific logic
17 and reason.

18 Q. And what you have presented
19 to the Commission is your hypotheses that you regard
20 as most reasonable in the case of each particular
21 child?

22 A. That is correct.

23 Q. And you have, in effect,
24 ranked them for us in levels of acceptability from
25 your point of view?

A. Yes, as best I can.



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Q. And that is much the same sort of procedure as you would expect any scientist, specifically a pharmacologist, to apply to this type of analysis?

A. Yes.

Q. Doctor, I have heard the name Dr. MacLeod mentioned.

A. Yes.

Q. I do not think he is to be called as a witness, or at least I have not seen his name suggested. Is he your immediate superior?

A. Yes, Dr. MacLeod is the Division Chief of the Division of Clinical Pharmacology at the Hospital.

Q. So you report to him, do you?

A. We work reasonably co-equally, but in terms of status, he is my boss in essence, immediately.

Q. Now, I gather that the appendix to Dr. Bain's report, the second appendix which has been referred to earlier in your evidence, was prepared by you and Dr. MacLeod?

A. It was prepared by the two of us in conjunction with discussions with other people involved in kinetic studies with digoxin and



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other compounds with our fellows. Our belief, and one of the recommendations, in fact, at the end of the report is that the only way to approach this kind of thing, in that no one is omniscient, is to try to work as a team approaching all of these matters, kicking ideas around, so that there was a great deal of discussion about what kind of issues had to be approached within the division as well as with people from outside the division.

Q. Well, it is fair to describe you and Dr. MacLeod as the two principal authors of that appendix, working in conjunction with your colleagues?

A. I believe that is a fair statement, sure.

Q. And that report itself, as I understand it, was prepared about a year ago; is that right?

A. I cannot give you the exact date. I could go back and check. It was basically within a very short period of time, several weeks to a month perhaps after the end of the preliminary hearings when the Research Institute asked us to undertake a quick review and see if we could come up with some initial recommendations.



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Q. That would be the summer of 1982?

A. Yes.

Q. And it is reasonably fair to say, is it not, that except for this pathophysiology question, the theory of Appendix 2 is much the same as the theory you have presented to the Commission today?

A. Yes, most of the kinetic concerns were the same. Again, we were very concerned that some of the approaches that had been taken were dependent on one particular view of kinetics and we were concerned that a general view of such issues should be taken with the broadest possible perspective.

Q. Well, the possibility of a single vial accidentally administered is something that is clearly set out in that appendix, is it not?

A. Yes.

Q. And that was a view you developed at the time, that is, over a year ago?

A. That is correct.

Q. And then what you have told us is that since that time, further information that has come to light in terms of your knowledge as a



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pharmacologist has suggested another explanation
which may apply in some cases?

A. Yes.

Q. And that is the very same
explanation that was advanced by Dr. Kauffman in
the Gary Murphy inquest?

A. Yes, and modifications thereof.

Q. And that theory, then, or
explanation is a fairly recent one in terms of
scientific knowledge?

A. Yes.

Q. Now, I wanted to be clear as
to exactly what it is that you have considered in
terms of coming to your opinion, that is, the data
that you have looked at, and it is clear that you
have looked at the levels obtained by the Centre
for Forensic Studies?

A. Yes.

Q. You have looked at the charts
of the five children that you have been dealing
with in your evidence?

A. Yes.

Q. That is the medical records
from the Hospital?

A. That is correct.



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Q. You have looked, as I understand it, from Appendix 2 at certain evidence given at the preliminary hearing into the charges against Susan Nelles, specifically, you looked at the evidence of Mr. Cimbura, Dr. Hastreiter and Dr. Ellis?

A. Yes, that is correct.

Q. I gather you have also read the evidence of Dr. Kauffman at the Gary Murphy inquest?

A. I was present at the inquest.

Q. You were present, I see. Did you give evidence there?

A. No, I was present at the autopsy and all the events surrounding that particular episode, but it was felt that it would be better to have Dr. Kauffman come in as an outside pharmacologist to provide testimony at that time.

Q. And you have also considered, I take it, some of the evidence that has been given in these proceedings to date?

A. To a very limited extent, only those things that either Mr. Lamek suggested or brought up as a result. I have not actually sat down and read any of the testimony other than Dr. Mirkin's initial discussion of the pharmacology



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of digoxin at the beginnings of the hearings.

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Q. Is there anything else, in particular, that you have looked at?

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A. That coupled with whatever literature is available and felt to be relevant, both past literature as well as very much current literature on a field that obviously is developing very rapidly.

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Q. Well then, I take it, one of the things, though, that you have done in the course of reading the evidence at the preliminary inquiry is that you have tested your hypotheses against the other hypotheses that have been advanced; is that fair?

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A. Yes, we looked at the issues that have been brought up with respect to kinetic considerations, but our real purpose was not so much to review what had gone on in the past but to establish a whole series of potentially testable hypotheses which might aid in further elucidation of the problem.

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We felt the obligation to look as broadly as possible, feeling that in essence a very broad view of the pharmacology had yet to be presented and to be worked with.



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Q. Well surely one of the things you have done, though, is compared your hypotheses to the hypotheses of other experts as they have been advanced at the preliminary inquiry?

A. Yes.

Q. And are you aware in that regard of the evidence of Dr. Hastreiter concerning administration or what he proposed as a hypothesis for the administration of digoxin in the case of Justin Cook? Do you recall what he said in that regard?

A. I do not recall that specific portion of the testimony.

Q. Well, I am not going to give it to you specifically, but I am going to give you the number of ampules which he posited as being an explanation for the level which was observed in Justin Cook. As I understand and read his evidence, he posited somewhere between 4 and 16 adult ampules as accounting for those levels, or 40 to 160 infant ampules. Let me deal firstly with the infant ampules.

Incidentally, do you recall that as being his evidence?

A. I do not recall the precise numbers, but I recall multiple vials in that general



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2 neighbourhood, yes.

3 Q. Well, I take it the 40 to
4 160 infant ampules you would just find absolutely
5 inconceivable as an explanation?

6 A. The volumes we are talking
7 about approach 10 to perhaps 40 millilitres per
8 kilogram of body weight, which is an amount that
9 could not be sustained by an infant with that kind
10 of heart disease. One could not do it, in essence,
11 nor is it reasonable pharmacologically to imagine
12 modelling where that amount could be given slowly.
13 The child simply would not have been able to survive
either volume-wise or concentration-wise.

14 Q. Dealing with the bottom of
15 Dr. Hastreiter's range in terms of adult ampules,
16 which is 4 -- the range was 4 to 16 -- I also suggest
17 to you that you would find 4 adult ampules to be
a highly unlikely hypothesis in the circumstances?

18 A. I think it is unlikely for
19 several reasons, which we have elucidated. One
20 obviously is the clinical status in that it is
21 unlikely that this child would have gotten down to
22 a steady state concentration of digoxin with the
23 nature of his heart disease, so that all the
24 calculations were based on the assumption of full
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I.14 distribution, which given the child's clinical status, seems rather unlikely. We have talked about the problems in terms of volume, the lower amounts we are talking about only 8 cc's, so that from a fluid point of view from the child's circulatory system, this would not be a problem. But again, it is a tremendously large dose from the point of view of trying to put that in over a reasonably brief period of time, either through intravenous needle or because of the propylene glycol related problems.

If that be the case, the blood levels never would have come down simply because of the probability of toxicity of the propylene glycol way before the drug had ever had a chance to distribute, and as such, again, coupling that with the physical difficulties of opening multiple vials, drawing them up, the time requirements and such, all of that becomes, to my way of thinking, very, very unlikely; still conceivable but very unlikely.



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Q. Well, given what you have said about the effect of propylene glycol, would I not be correct to understand that if you administered 4 ampules of adult digoxin to a child and did it in a relatively quick fashion, in a hurry.

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A. Yes.

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Q. You would expect death to occur literally in seconds because of propylene glycol?

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A. With those volumes in a child that size I would expect a very high probability of very rapid onset of toxicity, which again would preclude distribution of the drug. If we were dealing with 4 ampules it would produce astronomically high plasma concentrations, I can't give you a number now, but it would be orders of magnitude outside of what we are now talking about. And no tissue concentrations presumably because the tissue would die very rapidly.

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Q. And I can assume, Doctor, that what you have said with reference to the theory of Dr. Hastreiter in relation to Cook would also apply to his theory in relation to Miller, where he posited 10 adult ampules, or 100 infant ampules, what you have just said would apply equally, would it not?

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A. Yes, it would.

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J.2

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A. Yes, it would.

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Q. Doctor, you have spoken of medication errors, and you are obviously familiar with the report of Mr. Justice Dubin. Have you read the Report of The Hospital for Sick Children Review Committee?

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A. Yes, sir, I have.

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Q. Certainly I would have expected you to have read it as it pertains to pharmacology.

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A. Yes.

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Q. And we have been told by you and others that as a result of Mr. Justice Dubin's recommendations there have been radical changes in the system of pharmacology at the Hospital?

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A. Yes, that is correct.

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Q. Now, you referred to some of the medication errors that were referred to in the Report of the Committee. We have also heard evidence in these proceedings about some other medication errors and I want to take you to those.

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A. Yes.

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Q. The first related to a child called Antonio Velasquez, who died in August of 1980. Are you familiar with the circumstances of that child?

A. Only in the most superficial way.



J.3

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Q Let me put this to you. It is the evidence I believe that there was an apparent concern that the child was not responding, it appeared that it might have received an accumulation of too much codeine and a drug called naloxone was administered by a physician apparently at twice the appropriate dose.

A Yes.

Q That is on two occasions, twice the appropriate dose?

A Yes. Now naloxone is confusing in that regard. There is not really an appropriate or correct dose. What one is trying to do with a drug like that is to counteract the amount of narcotic present in the patient.

An example: while I was at Johns Hopkins we had a psychiatry resident who tried to commit suicide with Demerol that required dozens of times the amount of naloxone to bring his respiration back as it would have the amount of naloxone required to bring respiration back in somebody who took a much lower dose of Demerol. So it is a relative kind of situation. One usually starts off with the standard recommended dose, then may give another dose, a larger dose to see if in fact the patient responds.



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Q Well, that is fair enough what you have said; but as I understand it and I don't think there is any dispute about this, the doctor misunderstood, or mistook what the regular dose was initially, he gave twice as much as he was supposed to, is that your understanding of what took place?

A. Again I don't have any real firsthand information on that.

Q Well, given what you have said about how medication errors can occur in times of stress, tension at night and so forth --

A. Yes.

Q -- would you agree that that type of situation which we see in the case of this child Velasquez, would be a prime candidate for medication error when there is an emergency?

A. That type of situation certainly is, and there are data on that in newborn ICU's particularly.

Q In where?

A. In newborn ICU's.

THE COMMISSIONER: That was deliberate was it not, wasn't it?

MR. STRATHY: I think, Mr. Commissioner, we have not heard from the doctor himself but it



J.5

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2 wasn't deliberate. It is pretty clear it was
3 inadvertent I think, based on the memoranda that were
4 filed.

5 THE COMMISSIONER: Perhaps I will
6 leave that alone then. I thought he had decided to
7 give that dosage, and that dosage in better opinion
8 was twice as much as it should be.

9 MR. STRATHY: No, I think with respect,
10 Mr. Commissioner, the documentation seems to indicate
11 it was an error by the doctor as to what the appropriate
12 amount was.

13 THE COMMISSIONER: I understand it is
14 an error by the doctor but wouldn't that be
15 considered - when the doctor prescribes a certain
16 dosage would you call that an error, would that be an
17 error?

18 THE WITNESS: Incorrect dosage
19 prescribed, yes.

20 THE COMMISSIONER: I see, all right.

21 MR. STRATHY: Q. Certainly that would
22 be, by any pharmacologist's classification an error
23 where the physician mistakes the dosage he is supposed
24 to give?

25 A. Yes. In fact reasonably large
literature on dosage miscalculations in Intensive



J.6

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Care settings, where miscalculation of dose plus or minus a huge range up to tenfold occurs on the average of about 8 per cent in some units, that high, so that a fair number of calculation errors do indeed occur.

Q. That is in an ICU setting?

A. That is in an ICU setting. Again with stress and people moving very rapidly under situations where very rapid decisions have to be made. So calculation errors certainly are not at all infrequent.

Q. And indeed that type of situation of stress and having to move rapidly and so on is exactly the type of situation that you would have at a cardiac arrest?

A. Yes.

Q. A lot of people gathered around in small quarters, a high degree of tension, things happening very quickly?

A. Yes.

Q. We have also heard about a child called Kristin Inwood, and I think you obviously referred to her in your evidence. You pointed out that she received three times, I think your evidence was three times the amount of digoxin that she was supposed to receive because someone gave another



J.7

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child's dose to her?

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A. Yes.

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Q. That is your understanding?

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A. That is my understanding of that particular incident, yes.

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Q. And I believe there has been evidence in this regard that this occurred on an evening when another child, a child called Manojlovich, had a cardiac arrest, is that your understanding?

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A. I believe so, yes.

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Q. Once again in those sort of circumstances, emotional, high-pressured, at night, that would be a prime time for a medication error, wouldn't it?

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A. Yes, it would be.

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Q. And then you were referred to the report of Mr. Justice Dubin, at page 177, and you were taken through the evidence concerning Jonathan Murphy and the other children on Ward 7F who were the victims of a medication mix-up between epinephrine and Vitamin E?

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A. Yes.

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Q. And epinephrine as we have heard is simply adrenaline, is it not?

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A. Yes, the form that was in that



J.8

1
2 solution called racemic epinephrine is a special
3 preparation designed for inhalation, it is a mixture
4 of two different types of epinephrine basically, two
5 different isomers if you will of epinephrine.

6 Q But it is a kind of adrenaline?

7 A Yes, that is correct.

8 Q As you have pointed out this
9 was not simply one error, it was a number of errors
10 occurring over a period of time by a number of nurses?

11 A That is correct.

12 Q And apart from the similarity
13 in the bottles, do you know why it was that these
14 errors occurred?

15 A I can't say with any assurance
16 why they did. The bottles are similar, the medicines
17 smell different but often one doesn't smell the
18 medicine that one is giving. They have a different
19 consistency in that one of them is rather viscous
20 or thick flowing and one of them is rather liquidy
21 and smooth flowing. Why specifically that occurred
22 is very difficult to say, except that the two drugs
23 were available in the same place.

24 Q Let me ask you about that. Do
25 you know anything about where the two drugs were
located? Were the drugs stored alphabetically, for
example?



J.9

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A. I honestly don't know during those circumstances.

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Q. Was epinephrine supposed to be on the ward at the time?

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A. Again I am not sure whether that preparation was or was not being used for a specific child at that time. We would have to go back to the testimony that was provided.

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Q. Let me put this to you, if the medications were stored alphabetically on the shelf so you had the E's, epinephrine and Vitamin E I suppose.

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THE COMMISSIONER: That would be beside "V".

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MR. STRATHY: Q. Would that be one reason why you might have confusion if they were stored side by side on the shelf?

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A. Certainly, particularly given that one is dealing with labels that look rather similar in terms of colour. Again the nature of the labelling was such that one had stripes in pale blue and pale green, that were the same size, heading in the same direction. So that picking up the vial quickly and recognizing that the printing on the vial is small, sometimes difficult to read, that it



J.10

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2 is possible to confuse them. What is striking in
3 the episode is the fact that that confusion occurred
4 repeatedly.

5 Q But again you have told us
6 that mere fact or repetition is something with which
7 you are familiar, and I believe you mentioned
8 experience at Johns Hopkins of repeated medication
errors?

9 A Yes. We had one particular
10 episode when I was on the Pharmacy and Therapeutics
11 Committee when vials of Lidocane which would be used
12 as a local anaesthetic and vials of 50 per cent
13 dextrose or sugar had, one label was light yellow and
14 one label was medium yellow; they were the same
15 sized vials and we had two types of errors being done.
16 One was substitution of 50 per cent dextrose as a
17 local anaesthetic; one was the use of Lidocane in
18 diabetics who were hypoglycemic whose blood sugars
19 were low when they were meant to get epinephrine. In
20 fact we had a cluster of these events occurring over
21 a very short period of time within about a week,
22 several of these events occurring. One of them
actually occurring after recognition that this was
going on but nonetheless one still occurred.

23 Q How many events in total then
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J.11

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2 of these clusters?

3 A. I think there were six or seven
4 misadministrations, I don't remember the exact numbers
5 to be honest.

6 Q. Apart from your own personal
7 experience and the experience that is recorded in
8 the Dubin Report, you are aware of other incidents
9 in the literature of clusters of medication errors?

10 A. Oh, yes.

11 Q. Do you know at present - let me
12 take you back first of all to March, 1981. Do you
13 know in March 1981 how the medications were stored
14 in the pharmaceutical rooms in FA and 4B at the
15 Hospital?

16 A. I am not probably accurately
17 conversant on that to give you an accurate picture.
18 I think probably other people who were actually there
19 would be able to give you a much better idea.

20 The issue as I understand it is that
21 there were indeed multiple medications on the ward,
22 not in unit dose or pre made-up syringes, but rather
23 in vials which had to then be dealt with.

24 Q. On shelves in the medication room?

25 A. Presumably so.

Q. Side by side. My question is



J.12

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more specific I suppose. Do you know how they were organized on those shelves; for example, were they organized alphabetically?

A. I don't know.

Q. You put what I understand to be the current situation is that they are stored alphabetically in the medication rooms on those wards, that is you have the "E"s" next to the "F"s" and so on, is that your understanding?

A. Again, I don't have any specific knowledge of that. It varies, you know, from ward to ward in terms of how things are stored. I think you would have to speak with the pharmacist on the ward and ask how things are presently being done, and what difference occurred back at the time of these events.



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Q. Well, the reason I asked you all this, Doctor, is not simply idle speculation. You have put a hypothesis forward that digoxin may have been confused with one of the other common arrest medications and one of the common arrest medications we have seen is epinephrine?

A. Yes.

Q. Adrenalin.

A. Yes.

Q. And if you have digoxin and epinephrine sitting side by side on the shelf I suggest to you there is a possibility for a mix-up in the sort of tense frantic situation you have described?

A. If that were the case, and again, I have no knowledge of that specifically. That could indeed happen. The other issue is that at that time, and it is a major difference in the way drugs are handled in the hospital now, there were no prepared sealed boxes that contain emergency medications. The present situation is that there are red tackle boxes that look like fishing boxes basically that are sealed and when opened have an organized array of medications laid out. Those prepared boxes sealed in the pharmacy are



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2 delivered to the floor and then returned to the
3 pharmacy if they have to be opened for replenishment
4 didn't exist.

5 So that again medications had to
6 be diluted, medications had to be picked up off the
7 crash cart or someone might have to go into a
8 medication room to get extra vials of medication.

9 Q. Would you agree then that
10 in the pre-April, 1981 period where you were dealing
11 with crash carts which didn't have the type of set-
12 up you have described was a much greater potential
13 for confusion of medications?

14 A. This was a major concern
15 and the reason the sealed boxes were introduced.

16 Q. Now, Mr. Roland took you
17 through this, and I won't dwell on it, but it is
18 pointed out in the Dubin Report that in the course
19 of this whole epinephrine situation on Ward 7F it
20 was discovered that one child had accidentally
21 received digoxin when the child was not supposed to?

22 A. That's correct.

23 Q. And that was not with-
24 standing the fact that the entire Hospital must by
25 that point have been so concerned about digoxin that
it was on everyone's mind?



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2 A. That's correct, and there
3 were several other errors as Mr. Dubin indicated.

4 Q. Several other errors
5 concerning administration of digoxin when it wasn't
6 supposed to have been administered?

7 A. That is correct.

8 Q. And again this is
9 notwithstanding the fact that by then you were I
10 guess not on the unit dose?

11 A. Unit dose hadn't been
12 introduced but what had happened was that the
13 digoxin had become a controlled substance and that
14 multiple signatures were required for administration,
15 yes.

16 Q. And those other instances
17 were again patients who were not even supposed to
18 be receiving digoxin?

19 A. In at least one instance,
20 yes.

21 THE COMMISSIONER: Whenever you
22 want, Mr. Strathy.

23 MR. STRATHY: I beg your pardon?

24 THE COMMISSIONER: Whenever you
25 want.

MR. STRATHY: Well, this might



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be a good time, Mr. Commissioner.

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THE COMMISSIONER: Yes, all right,

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2:30 then.

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MR. TOBIAS: Mr. Commissioner, could

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we just make a quick poll?

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THE COMMISSIONER: We took one

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yesterday which really turned out to be one of the

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less reliable polls. We can try again though and

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see what happens.

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MR. TOBIAS: At the risk of

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repeating the error perhaps it might be helpful.

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THE COMMISSIONER: Yes, all right.

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Mr. Hunt?

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MR. SCOTT: Lawyer's errors don't

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seem to count in quite the same way.

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THE COMMISSIONER: No.

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MR. HUNT: I would be interested

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in knowing how much longer Mr. Strathy is going to

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be?

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THE COMMISSIONER: Well, I had

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better ask Mr. Strathy first, how long are you going

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to be?

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MR. STRATHY: Well, I think I will

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be another 15 to 20 minutes probably.

THE COMMISSIONER: Yes, all right.



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2 Mr. Hunt?

3 MR. HUNT: I will be 15 minutes.

4 THE COMMISSIONER: Yes. Are all
5 the other estimates of 15 minutes, have they changed
6 up or down since the last time. Has anybody anything
7 different?

8 MR. YOUNG: I don't think we gave
9 an estimate yesterday, Mr. Commissioner.

10 THE COMMISSIONER: Yes, all right.

11 MR. YOUNG: But after discussing
12 this matter with Mr. Percival I don't believe we are
13 going to have any questions of this witness.

14 MR. SCOTT: Well, there are some
15 interesting things. Mr. Manning has completely
16 disappeared. Mr. Percival has receded to the point
17 of disappearance and I am fading quickly. Only Mr.
18 Lamek remains as one of the senior members of the Bar.

19 THE COMMISSIONER: Well, he is under
20 contract but he is disappearing tomorrow for a
21 competitor he is appearing before some people at
22 the Court of Appeal.

23 MR. SCOTT: Well then, we will have
24 a day tomorrow.

25 THE COMMISSIONER: We will have a
day tomorrow. Somehow or other I don't seem to have



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2 managed a substitute yet. What do you say, Mrs.
3 McIntyre?

4 MS. McINTYRE: I may be somewhat
5 longer than the 15 minutes I predicted, depending
6 on what the questions are that are asked before me.

7 THE COMMISSIONER: Yes, all right.
8 Mr. Olah?

9 MR. OLAH: Things haven't changed,
10 I expect to be 15 minutes and I probably will be right
11 on the 15 minutes.

12 THE COMMISSIONER: Yes, all right.
13 Miss Jackman.

14 MS. JACKMAN: I will be about 15
15 minutes, Mr. Commissioner.

16 THE COMMISSIONER: Well, that gives
17 you an idea, and I haven't got to the parents yet
18 but that gives you an idea.

19 MR. TOBIAS: Thank you, Mr.
20 Commissioner.

21 THE COMMISSIONER: It doesn't
22 look as though we will make it this afternoon. I
23 am of course very much concerned and it is important
24 for Dr. Spielberg because you are very heavily involved
25 in this study that comes on on Monday, are you not?

THE WITNESS: Yes.



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2 THE COMMISSIONER: So, we have to
3 finish tomorrow no matter what happens.

4 So, if there is some danger we
5 may even sit late tonight, I don't know, but I
6 don't think there is any danger.

7 THE WITNESS: I do have a clinic
8 this evening.

9 THE COMMISSIONER: What do you mean
10 by this evening, what time?

11 THE WITNESS: Seven. I would like
12 a chance to eat in between.

13 THE COMMISSIONER: Well, we will
14 give you a chance for something at 6:45.

15 All right, until 2:30.

16 ---Luncheon recess.
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---On resuming at 2:30.

THE COMMISSIONER: Yes, Mr. Strathy.

MR. BROWN: Mr. Commissioner,
before we start, I have been able to finalize hope-
fully a date with Mr. Percival's office, providing
it is convenient with everyone, and the date proposed
is next Wednesday, the 2nd, I believe, of November.

I understand that you originally
requested that the argument be made starting at
3:45. That will prove to be difficult that day and
I suggest that the argument start at 4:30.

THE COMMISSIONER: Well,
unfortunately, Wednesday - when is it, the 2nd, did
you say, or the 9th?

MR. BROWN: I believe that is the
2nd.

MR. YOUNG: Yes, the 2nd of
November.

THE COMMISSIONER: Well, if it
starts at 4:30 - well, I know I shouldn't allow myself
a social life but I did have some hopes of being
away from here at 5:30. Is that not going to be a
likely possibility?

MR. BROWN: Well, I know Mr.
Sopinka has engagements shortly thereafter, so, I



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2 expect he will be short. He has engagements later
3 on the evening, so, I expect he will be brief. There
4 has been some difficulty planning a date convenient
5 for counsel also and I have conferred with some of
6 the other counsel on that date and it is convenient
7 for them.

8 THE COMMISSIONER: That is the
9 2nd at 4:30, did you say?

10 MR. BROWN: The Wednesday the 2nd
11 at 4:30, yes.

12 MR. STRATHY: Mr. Commissioner,
13 for those of us with less exotic schedules than
14 Mr. Sopinka, the only problem I can foresee is that
15 if we start at 4:30 with all of who may want to
16 make submissions---

17 THE COMMISSIONER: No, I don't
18 think 4:30 is realistic.

19 MR. SCOTT: Why does it have to
20 be Wednesday and why does it have to be 4:30. I
21 mean, to have a social engagement is an achievement
22 these days and I don't think it should interfere.

23 THE COMMISSIONER: Yes, well, I
24 agree with you, Mr. Scott, I don't think 4:30 is
25 realistic. 3:30 I thought was ---

MR. SCOTT: It is rather early for



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2 a social occasion; 5:30 I understand.

3 MR. YOUNG: Mr. Commissioner, I
4 don't want you to think that we are getting in the
5 way of your latter engagement. Mr. Percival has
6 absolutely cancelled any plans that he may have.
7 We were available at 3:30 or 3:45 as you suggested
8 but I believe it is Mr. Sopinka who has another matter.

9 THE COMMISSIONER: Well, he's got
10 a small matter in Newfoundland, I read in the papers.

11 MR. YOUNG: No, not on that date.

12 MR. BROWN: He has, on the Tuesday,
13 Wednesday and Thursday a Disciplinary Hearing at the
14 Convocation.

15 THE COMMISSIONER: I take it he is
16 not the accused.

17 MR. BROWN: I hope not. If that
18 is inconvenient, if I may suggest that perhaps we
19 would have to consider some other date, and possibly
20 a Friday.

21 THE COMMISSIONER: You can unconsider
22 that one immediately.

23 MR. BROWN: Well, there are
24 difficulties then.

25 THE COMMISSIONER: The only thing
is, the 11th is a holiday and I don't think we will



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2 be sitting on that day. Well, he has no other time
3 except 4:30 on the 2nd of November, is that right,
4 is that what you are telling me?

5 MR. BROWN: Well, certainly as far
6 as next week and I understand there is a long trial
7 commencing the following week. Also, we would like
8 if possible to submit our argument to you around the
9 time that you entertain written submissions on the
10 other points so that all these other matters are dealt
11 with at one time.

12 THE COMMISSIONER: Well, I really
13 don't think 4:30 is realistic and I think you had
14 better just go back to him and see if you can't sort
15 out some other date earlier in the afternoon because
16 I think we are going to have a terrible time getting
17 the rest of the counsel to agree to 4:30, where, if
18 they do agree they will feel put upon.

19 So, try and find some date that
20 is available to him and, I don't care, any time from
21 Monday to Thursday but not Friday. I don't mind,
22 we could start at 9 o'clock in the morning, I
23 suppose that is a possibility too.

24 MR. BROWN: I will go back.

25 THE COMMISSIONER: And see what
you can do. But it has to be, I think 3:30 is the



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last realistic time that we can have in the day.

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Does anyone else have any views on
this matter.

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Now that we have expanded it a
little bit a lot of other people may have views.

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MR. OLAH: Mr. Commissioner,
I assume that you want the issue of notice argued
at that time though?

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THE COMMISSIONER: At the same time,
yes.

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MR. OLAH: I would think that
argument would be fairly protracted and to start
at 4:30 would probably leave us here until about
8 o'clock.

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THE COMMISSIONER: Yes. Well, that
was one of the reasons where I think 3:30 - in fact,
I don't mind if we could even put the whole afternoon
if necessary. So, you can see if there is an after-
noon likely available. You say that on that day he
is on Discipline Hearings, is he?

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MR. BROWN: That is correct, Mr.
Commissioner.

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THE COMMISSIONER: Well of course
they may always be finished and then they may not
be finished, so, I don't know what to do about that.



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All right. Well, I think we will just not make a date and we will leave it until you can get something more realistic.

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MR. STRATHY: I think Mr. Roland wants to give us some show and tell, Mr. Commissioner.

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MR. ROLAND: Yes, Mr. Commissioner. This morning as you will recall, there was some discussion about an IV apparatus. We have now been able to produce it for you freshly out of the package a brand new IV apparatus and perhaps Dr. Spielberg you could describe how all of this works.

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THE WITNESS: All right. This being the buretrol which, as you can see, has graded amounts in here up to 150 millilitres. So that, for example, let's say we are working in eight hour periods of time and a baby you might fill eight hours or four hours with a fluid in here to prevent the entire IV solution from running in. Obviously this amount of liquid is a great deal of liquid for a small baby. In practice, what one has to do hopefully is open the package. How do these open. You will have to excuse me, I am used to the IV packaging, which is a little bit different. Okay, the package opens this way and then just to stand up here. This portion of the system has to be



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2 connected.

3 THE COMMISSIONER: May I ask what is in that
4 thing at the moment?

5 THE WITNESS: This is a bottle of
6 3.3 per cent dextrose and .3 per cent sodium chloride,
7 which would be a standard type of intravenous
8 solution that might be used on the wards and then
9 you have to pull that off. Then one has to insert -
10 hopefully we would have a bit better sterile technique
11 than that - this into the bag. Now, one thing you
12 should be aware of, Mr. Commissioner, at the time,
13 and still to a certain extent, very often IV solutions
14 had to be mixed on the wards. For example, if a
15 baby was to receive potassium chloride the nurse
16 would then have to inject potassium chloride through
17 here in the bag and one of the hazards of doing
18 that is that the potassium chloride is very heavy
19 compared to the IV solution and sometimes it can
20 layer out on the bottom. So that if you open this
21 you might end up getting, up here, a solution of
22 potassium chloride.

23 In any case, what you would do,
24 you would make up your final IV solution and then
25 it would have to be vigorously mixed up and down
to assure yourself that it was well mixed. Then the



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IV solution itself would be - whoops, we have to
close it down here or we are going to have a mess.

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If anyone would like to volunteer for the actual
IV portion - no, okay.

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THE COMMISSIONER: I want to know,
that is the position?

THE WITNESS: Now, this is the bag
and often the bag would be hanging on the pole. Some-
times it would be up this way so that the bag would
be hanging on one side and the buretrol on another
side to prevent accidental dumping. But the practice
would be to fill the buretrol to the desired level,
we will say here 30 millilitres, for example, and
then to be sure that this is closed so that the rest
of the bag might not inadvertently, if there was an
accident down here, end up giving too much fluid to
the infants.

Now, as you can see, there are several
different ports or rubber stoppers along this process
where you might be able to add a medicine. We have
said it might be added to the bag directly through
here. You might inject through here into the buretrol
itself.

Now, as you can see, the line itself,
this IV line down here is rather long. The volumes
vary. Many of them are about 10 millilitres. I am
not sure about this particular brand, but as you can
see there are several places along the line here and
down here where a drug might be administered. So you



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have the bag itself, into the buretrol, and at least two different places on the line. For example, if you wanted something to run in rather slowly, you might put it higher up in the line. It would then gradually go in as the IV solution ran out.

THE COMMISSIONER: But it would obviously go in much faster and much sooner than it would if you put it in the bag?

THE WITNESS: Than it would in the buretrol or in the bag, certainly.

Now, in addition to that, here is an IV needle. The needle itself would go into the patient's vein and then the IV itself would be hooked into the end of the needle.

Now, under certain circumstances there might be an additional piece put in here between these two, which would look in the shape of a T, which might be another site for injection. So that we could have injection sites as low down as very close to the baby.

THE COMMISSIONER: And the closer you get, the faster it will take effect?

THE WITNESS: The time that it will take to get from the injection to the baby becomes progressively faster, yes, sir.



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THE COMMISSIONER: What about the bag
and the buretrol, the buretrol sort of controls the
rate, does it?

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THE WITNESS: Well, it controls the
total amount that might go in. To control the rate
we have a switch here that, as you can see when I
open it, you begin seeing drops come out and you can
control the rate by adjusting the number of drops
coming out like that, slowly -- that is very slowly --
or very rapidly, or there is sometimes a machine that
is inserted into the line called an Ivac or Imed,
it depends on the type of pump, and that will pump
the -- it will milk this at a specific rate. So you
would set it at 2 millilitres an hour or 10, or
what-have-you.

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THE COMMISSIONER: And it makes no
difference whether you put it, I take it, in the
buretrol or in the bag except perhaps the distance
between them ---

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THE WITNESS: Right, and the
concentration. For example, if you wanted to give,
we will say a drug like ampicillin, an antibiotic, we
typically would administer a drug like that over 20
minutes. So you would put the ampicillin, the total



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dose that you wanted, in a volume that you would normally deliver over 20 minutes. If you put it into the whole bag, the whole bag might not be used in a day. So that standard drug administration might well be via this mechanism.

On the other hand, if you are doing a medicine at a continuous rate like theophylline, for example, used in asthma, under those circumstances you would often make up a whole bagful at a constant concentration and that would then be administered continuously over a day's time. So it depends on how you are giving the medicine, which you would choose, the buretrol, the bag, one of the IV ports.

In an emergency situation where you wish to give a drug, for instance, like Lasix very quickly, you would give it down low in the line or if there is a T-piece down here, you might give it directly into the T-piece, this little additional portion.

THE COMMISSIONER: What about that apparatus, Mr. Roland, do you want to part with it?

MR. ROLAND: Yes, let us mark this as the next exhibit.

MR. TOBIAS: I wonder if the doctor might just point out where is the bolus?



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THE WITNESS: There is not such a
physical item.

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MR. TOBIAS: Okay, well perhaps you
could explain that.

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THE WITNESS: If, for example -- what
a bolus means is just, if you will, a small quantity
of drug or solution given rapidly. One could
administer a bolus of drug presumably at any of these
injection points.

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Now, for instance, if you very rapidly
inject it up here at this higher point, then that
would end up tending to be diluted somewhat by the
remainder of the solution in the line and go in some-
what more slowly. If you injected it down here,
there would be progressively less dilution and more
rapid running in, again depending on the intravenous
rate.

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The other possibility is if there was
a T-piece right here, you would actually be providing,
since the dead space or the volume in this portion
is very, very small, pure drug would go in very
quickly, or under certain circumstances in particular
emergencies one might actually go so far as to
disconnect here and inject directly. That is a bit
more unusual circumstance.



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THE COMMISSIONER: What number are we at?

THE REGISTRAR: 227.

THE COMMISSIONER: 227.

MR. ROLAND: I am sure Mr. Elliot will be delighted to receive this.

--- EXHIBIT NO. 227: IV apparatus.

THE COMMISSIONER: When people have been saying to us, they have been saying to us inject into the bolus, they really do not quite know what they are talking about?

THE WITNESS: The terminology is inject as a bolus, not into the bolus.

THE COMMISSIONER: As a bolus into the line?

THE WITNESS: A bolus into the line, correct. We often tend to use terms that are a bit obscure until demonstrated.

THE COMMISSIONER: You are not alone. Yes, all right, now, Mr. Strathy, do you want to return?

MR. STRATHY: Q Doctor, just continuing briefly on the subject of medication errors, I have reviewed the Dubin Report, and there is a comment at page 195 to the effect that there was no



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way for the Committee to accurately determine the actual experience relating to medication errors at The Hospital for Sick Children. Incident reports reflect, we think, only a small percentage of such errors, and I take it you would agree with that observation?

A. Yes, all the studies which have examined the ratio of incident reports which can be ascertained by surveillance compared to reported incidents show that the reported incidents are a very small fraction; in one study as low as one-thousandth of the actual number.

Q. And your own personal observations would support that as well?

A. Yes, that is correct.

Q. I suppose in the first place the person may not even realize that they made a mistake?

A. Yes, I think that is frequent.

Q. I am sorry?

A. I believe that is a frequent phenomenon, particularly if nothing adverse results.

Q. And secondly, they may realize they made a mistake but failed to document it?

A. Yes.



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Q Now, the Dubin Report also goes
on at page 195:

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"From our analysis there is no
reason to believe that the percentage
of medication errors at The Hospital
for Sick Children is anywhere as high
as what was reflected in the above
referred to text ... "

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which incidentally is the text that you referred to
this morning:

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" ... but there are still far too
many medication errors for a hospital
of the calibre of The Hospital for
Sick Children."

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Then also at page 207, near the middle of the page,
Mr. Justice Dubin said:

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"Prior to March 1981 the pharmaceutical
services at The Hospital for Sick
Children were not up to the standards
required for a hospital of its size
and complexity."

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Would it be fair to say that based on what you have
seen, you would regretfully agree with those
observations?

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A My personal experience is such



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that I was not here when the pharmacy was operating
that way.

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Q. I realize that.

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A. I would imagine ---

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MR. SCOTT: Well, Mr. Commissioner,
just before the question is answered, we are not
going to cross-examine on Mr. Justice Dubin's report,
are we?

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THE COMMISSIONER: No.

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MR. SCOTT: It seems to me he has
made findings. They are before you and you are
obliged to take them into account.

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THE COMMISSIONER: Yes, I have to
accept those findings, and if I did not have to
accept them, I still would accept them anyway because
I have enough problems. The only relevance of all
of this, of course ---

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MR. SCOTT: It seems to me that I have
to accept them.

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THE COMMISSIONER: Yes. Well, the
only relevance of this, though, is as to the incidence
of error.

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MR. SCOTT: I would not like, and I am
sure my friend does not intend, I would not like a
poll of the witnesses to be taken as to whether they
agreed or not as to what Mr. Justice Dubin said, and



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2 it seems to me that that is what this question is
3 directed to: does he agree with what Mr. Justice Dubin
4 said? Now, if the witness was not there at the
5 relevant time, perhaps it is all premature.

6 THE COMMISSIONER: Well, I think there
7 is something in that, Mr. Strathy, because I really
8 cannot go behind what -- at least if I can go behind,
9 I do not intend to unless there is some demonstrable
error.

10 MR. STRATHY: Well, I do not want to
11 make a big issue of it, Mr. Commissioner, but the
12 witness has testified that in his view a medication
13 error is something that we should seriously consider
14 in the case of some of these deaths. Mr. Justice
15 Dubin concluded there were too many medication errors
taking place in the relevant time.

16 THE COMMISSIONER: No, but if I am
17 going to accept what he said, you really are not
18 furthering your cause by asking him whether he agrees.
19 He probably will answer yes. If by any chance he
20 answered no, it would hardly help, though, would it?

21 MR. STRATHY: Well, I suppose if you
22 are telling me, Mr. Commissioner, that you are
23 prepared to accept the conclusion of Mr. Justice Dubin
in that regard ---
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THE COMMISSIONER: Well, I think the Terms of Reference really suggest politely that I should not even question them, I should not go into them, I should accept those as facts. Obviously, if it turns out there is a demonstrable error, I may have to go into it. But so far nobody has shown one.

MR. STRATHY: All right. Well, I will not pursue that particular point further, then.

Q. But I would like to suggest this to the witness, and perhaps comment to Mr. Scott that I think the witness and the Hospital have been very fair in presenting this evidence to us because it seems to be highly relevant evidence for the Commission, and I suggest to you, Doctor, that it is not a happy conclusion for you that medication errors of this nature would be going on at the Hospital?

A. It is never a happy conclusion that errors occur. The positive side is indeed that a great deal has happened subsequently to correct and to improve the system as much as possible.

Q. Would it be fair to say as a scientist and as a responsible physician at the Hospital you consider it an obligation to bring to the attention of the Commission the views that you have with respect to medication errors?



BB.11

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A. Yes.

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Q. Now, let us turn to another

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area, then, and that concerns what -- I am trying to

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remember your definition or word is pathophysiology.

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I have referred to it in my own notes as the Gary

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Murphy effect or whatever we saw in Gary Murphy. Are

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we talking about the same thing?

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A. Well, we are talking really not

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only what happened in Gary, but a variety of different

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phenomena, not many of which we understand yet, all

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of which or any of which individually or in combination

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could lead to abnormal release of a very small

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fraction of digoxin or produce artefactually high

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values.

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Q. All right. So the thing that

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is happening, however, is a release of digoxin from

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the cells to the blood, is that ---

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A. This is the present leading

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hypothesis. There also may be such things as

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accumulation of metabolites in an abnormal pattern

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which changes things. We are not scientifically 100

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per cent sure. What we do know is that our digoxin

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readings go up.

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Q. So the overall phenomenon, however,

is this extra release of digoxin into the blood?



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A. We believe that that is playing a role in the kinds of phenomena that we have been talking about, yes.

Q. And Gary Murphy is just one exemplification of that phenomena?

A. Yes. There is now published literature on renal effects and questions that we have to raise on other patients we have seen over the last numbers of years.

Q. Now, you mentioned that with respect to Gary Murphy you were present at the autopsy?

A. Yes, I was.

Q. Why was that?

A. I was called I suppose around one in the morning by the cardiology Fellow that the baby had died and that during the process of doing the routine postmortem digoxins which had been mandated, a very high digoxin level came back from the laboratory. They did not know how high it was, but it appeared to be very high and what should they do. I came in to assist in trying to collect samples and to see if we could find out what had happened to the child.

Q. And I take it at that time,



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obviously, the immediate concern was some type of
large administration of digoxin?

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A. The first thought that one had
to have at that moment, facing what appeared to be
and our belief at that time was a level, in any case,
above 20 nanograms per ml, was that we certainly had
to rule out an administration of an excessive amount
or a dose that should not have been given to the
child at that time.

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Q. You said that you were also
present at the coroner's inquest in relation to
Gary Murphy?

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A. Yes, I was.

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Q. And you heard Dr. Kauffman give
his evidence at that inquest?

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A. Yes, I did.

Q. And did you agree with it in
substance?

A. Yes, I believe that with the
analysis and with the information available, going through
each of the potential hypotheses as to how this level
was arrived at, I believe his analysis was the best
possible answer that we could have for this particular
set of events.



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Q. Now, Dr. Kauffman did as you did; that is, posit a number of hypotheses and, as I recall it, his fifth hypothesis was this debinding effect.

A. Yes.

Q. And that, you agree, is the most plausible in the case of that child?

A. I believe it is our best explanation to date, yes.

Q. Just so I am clear, however, this debinding, as you have told us can occur in ways other than - or you believe it may occur in ways other than what was posited in the case of Gary Murphy?

A. Yes. We have data, for example, that different drugs can displace digoxin from binding, particularly quinidine, and a number of other agents may do the same kind of thing. We know that a variety of processes may influence the binding site for digoxin, sodium ATP, potassium ATPase and, at present, all we can do is list a huge number of variables, as we did on the board in the last several days, which might influence that binding or debinding process.

Q. Do I understand one of the things - without going into it in detail, doctor, one of the things that can potentially have a debinding



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2 effect is the defibrillation and cardiopulmonary
3 resuscitation?

4 A. We don't know that for sure
5 yet. That has been one of the things that has been
6 postulated. There are, at least to my knowledge to
7 date, no hard data on the effects, for example, of
8 the use of either defibrillation paddles - which would
9 be external electric shock to the chest, internal
10 electric shock in an open chest - or, for example, as
11 in several of these children, the insertion of pacing
12 wires within the chest. We do know that defibril-
13 lation electrically can cause release of a variety of
14 different intracellular enzymes from cardiac cells,
15 for example, creating impossible kinase or CPK,
16 which says that some tissue damage results from that
17 kind of an electrical shock, which is being used to
18 convert the patient into normal rhythm. What that
19 means with respect to digoxin has to be pursued in
20 future scientific studies.

21 Q. To put it simply, doctor,
22 it is a theory that has been postulated but all the
23 data is not yet in?

24 A. We have no real data yet, no.

25 Q. And just on that point of
the phenomenon of debinding, do I understand that that



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2 is something that can occur prior to death as well
3 as after death?

4 A. It appears both from the
5 drug studies, the phenomenon with renal failure, the
6 patients reported by other groups and now our own
7 experience with several patients that, under circum-
8 stances - and again we can't define all the
9 variables responsible - that it does indeed happen
10 in that digoxin levels can increase despite lack of
administration.

11 Q. During life?

12 A. During life.

13 Q. You mentioned your experience
14 since Gary Murphy, and you gave us several examples.
15 One that came to my mind immediately was the 11 level
16 during life, which you mentioned, and I believe you
said you didn't have a post mortem level in that case.

17 A. There was no post mortem
18 done on that child.

19 Q. Certainly, if one posits
20 a doubling or a tripling of levels post mortem as
21 opposed to ante mortem, that 11 ante mortem level
could result in a 22 or 33 post mortem?

22 A. Hypothetically. We really
23 don't have any -- obviously, we don't have the data
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2 that we would need on that child. As we said, some
3 children will not increase, other children may
4 increase two or threefold.

5 Q. Certainly, what we know of
6 the phenomenon tends to suggest, on an average, there
7 is an increase post mortem?

8 A. Yes. Most of the data
9 suggests that.

10 Q. In the order that I have
11 suggested to you?

12 A. And, again, with a lot of
13 variability but, certainly, threefold has been
14 reported as a number appropriate, as we have been
15 talking in terms of multiplier in children.

16 Q. And those levels of 10
17 ante mortem and 30 post mortem are not out of line,
18 really, with what we saw in the case of Kevin Pacsai?

19 A. Numerically, they are
20 reasonably similar.

21 THE COMMISSIONER: Could I interrupt
22 just for a moment.

23 Your theory doesn't involve the
24 manufacture of more digoxin, does it? It really
25 is displacement from one area of the body to the other?

THE WITNESS: Yes.



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THE COMMISSIONER: The theory is never given, other than substance X, that the body will produce digoxin on its own?

THE WITNESS: That has been something speculated about under certain circumstances, mostly in the renal failure patients, whether some patients, because of their genetic makeup as well as their disease state, might end up accumulating some of this substance X as well as --

THE COMMISSIONER: Apart from substance X --

THE WITNESS: Yes.

THE COMMISSIONER: Apart from substance X, which apparently is an infant phenomenon?

THE WITNESS: Well, it has now been demonstrated in adults as well.

THE COMMISSIONER: Occasionally, yes.

THE WITNESS: Yes.

THE COMMISSIONER: Substance X, apart from that, there is no suggestion that digoxin can be produced by any process other than administration?

THE WITNESS: Digoxin, per se, no.

THE COMMISSIONER: Yes.



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THE WITNESS: What we are

talking about in these situations is, as you stated,
a redistribution from one tissue to another tissue;
the second tissue being serum, which we measure.

MR. STRATHY: Q. In the context
of your review of the recent information at the
Hospital concerning this pathophysiology, you mentioned
the case I have just spoken of and another one in the
ICU; then you said there are other infants but you
didn't go into them.

I wonder, it would be of interest
certainly to me to know what your observations were
in other infants; how many other infants there were,
without going into the details, doctor; generally.

A. Basically, there have been -
and again, I am sorry, I really don't have accurate
numbers of patients, but there have been a reasonable
number of incidents where we have been asked to
consult on patients, usually terribly sick infants,
in whom digoxin will be stopped and, the next day,
the digoxin level will be slightly elevated and then,
gradually begin to come down. These are usually
reasonably small increases and, yet again, we have
come to the point where beforehand we would have
thought these increases would be very unlikely to



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2 occur. Now, it is becoming more or less our expecta-
3 tion that, in certain very ill infants - and certainly
4 not all, because this does not happen in all infants;
5 it is obviously going to be dependent on a whole
6 series of different phenomena occurring which we
7 cannot yet define. In some infants that very process
8 will occur, usually, to a very small extent. In some
9 infants, we have seen up to a doubling in life, and
those are the two infants that we presented.

10 Q. When you say a reasonable
11 number of infants, can you give us an idea of how
12 many you are talking about?

13 A. I really would have to go
14 back and check. It has probably been in the range of
15 about half a dozen infants over the last six months.

16 Q. Thank you.

17 THE COMMISSIONER: It is pretty
18 rare because we haven't seen it and I don't remember
19 having seen it in any of these charts that we were
20 looking at. Whenever there was a 'hold', there was
a gradual reduction.

21 THE WITNESS: Yes, sir.

22 THE COMMISSIONER: So, I would think
23 that is the normal thing; it would be very exceptional
24 to find it did increase?
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THE COMMISSIONER: It wouldn't be that outrageous for it to be, I suppose, building up in certain cases? It could still build up in the blood over a period of six hours?

THE WITNESS: Certainly, you know, in the short periods of time that we are talking about, absorption and things like that, yes.

THE COMMISSIONER: Yes.

THE WITNESS: These are situations where we will see levels continue to increase for a day or so after stopping administration.

THE COMMISSIONER: You have given us those examples --

THE WITNESS: Yes.

THE COMMISSIONER: -- in Baby A, B and C. I don't remember seeing that in the charts on any of the babies that we have been looking at, so I suppose it is a rare phenomenon.

THE WITNESS: I don't know which -- the 30 some odd charts that were looked at? I don't know which charts were looked at.

THE COMMISSIONER: We looked at them all. They don't all, of course, have this problem.

THE WITNESS: Yes.



CC9

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2 THE COMMISSIONER: But those that
3 we did look at that there was a 'hold' any time during
4 life that they took their reading again after that,
5 it was reduced.

6 THE WITNESS: Again, I have no
7 real idea what kinds of frequencies we are talking
8 about. I think one of the issues is one begins to
9 see these things more as one begins to recognize that
10 they occur. Frequently, you know, small increases;
11 say, 10, 20, 30 per cent, would often be attributed
12 to error in technique in the lab, or whatever, within
13 the range of assay. But then as you begin to
14 follow these babies, you begin realizing a real
15 phenomenon.

16 The large increases, such as we
17 have talked about, are indeed probably uncommon.
18 I doubt if they are rare. Most of the diseases that
19 I cited occur one in a thousand, one in ten thousand,
20 and I collect sizeable numbers of such patients in a
21 year because we see a great number of patients.
22 These phenomena are clearly more frequent than that
23 but beyond that, it is very difficult to say.

24 MR. STRATHY: Q. Doctor, we have
25 heard, in my recollection, that the RIA method of
immunoassay on digoxin did not come into medical use



CC10

1 until the early 1970s. Is that your best recollection?

2 A. Somewhere in that range, yes.

3 Q. So, really, when you re-
4 ceived your Ph.D - I see, at the University of
5 Chicago - in Pharmacology in 1971 --

6 A. Yes, sir.

7 Q. -- since the time that you
8 received your Ph.D., RIA has become a common practice
9 in hospitals, and I assume the RIA method has resulted
10 in a fairly significant increase in medical knowledge
11 about digoxin?

12 A. I think that is fair.

13 Q. After all, it now enables
14 you not only to detect the drug but to measure it
15 and, in fact, monitor the effects of the drug.

16 A. Yes.

17 Q. Let me deal very briefly
18 on just a few points that you mentioned with respect
19 to each child, and I certainly don't want to go over
20 what you have already said.

21 Let us start with Justin Cook. I
22 gather from what you have said, you considered the
23 possibility of an inadvertent administration of
24 digoxin to be entirely plausible in the circumstances
25 of an arrest, as occurred in that particular case?



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CC11 2 A. Yes. I think that is a
3 very reasonable possibility.

4 Q. And you mentioned, I gather -
5 I wasn't here again on Monday when this matter came
6 up. You mentioned that the Child Cook received a
7 drug called lidocaine.

8 A. Yes.

9 Q. Which was not recorded in
10 his chart.

11 A. Yes, that is right.

12 Q. And do you know how you
13 became aware that the child received lidocaine?

14 A. This was mentioned in
15 Mr. Cimbura's report, actually, in that he was doing
16 assays not only for digoxin but potentially for other
17 types of drugs, and lidocaine was indeed found in
18 therapeutic concentration.

19 Q. Now, you suggested, I believe,
20 that the fact that lidocaine was administered to the
21 child would not surprise you.

22 A. No. In fact, the drug
23 might frequently be used during a resuscitation pro-
24 cess if the baby exhibited certain types of cardiac
25 arrhythmias.

26 Q. So the fact of the lidocaine



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being there may on the one hand simply indicate that the nurse, whoever was making the notes, did not record it?

A. Yes. And that frequently again occurs during emergency situations of resuscitation. Sometimes things are indeed left out of the record.

Q. And the other possibility which we have to at least consider is the possibility that lidocaine was administered inadvertently as well?

A. That is conceivable.

Q. It is a hypothesis you have to consider, do you agree with that?

A. Yes. If we have no clearcut indication for how it was ordered or why it was ordered, we don't know. My supposition would be most likely that it was done intentionally in the course of resuscitation.

Q. Now, turning to Allana Miller - and we have your evidence on that - the only point I wanted to ask you was with respect to lasix and the administration of lasix.

I think perhaps the Commissioner had suggested to you that it was rather late in the day to be coming out and referring to this lasix



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CC13 2 matter, but I take it, really, all you were suggesting
3 was that --

4 THE COMMISSIONER: I said it was
5 early in the day, and it was a theory that had been
6 developed --

7 MR. STRATHY: I am going to suggest
8 to the witness that the theory of inadvertent admini-
9 stration had been developed over a year ago, back in
the summer of 1982.

10 I hope the reporter gets your
11 answer down. I take it you are answering?

12 A. That is correct.

13 Q. All you were saying was
14 that, in reviewing the charts and seeing there was
15 an administration of lasix, it provided the opportunity
for the error to take place?

16 A. Yes. The timing was
17 reasonably consistent with many of the things that we
18 have been talking about and again such an admini-
19 stration of a drug provided the opportunity for error.

20 Q. The other opportunity which
21 was there and presumably which was ample was during
the resuscitation itself?

22 A. Yes.

23 Q. And again in the case of
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Kristin Inwood, lasix, in your view, simply provided
an opportunity for an error to take place?

A. Exactly. Certainly, not
the only one and, as we said, it could have been
before or after. But, again, if a drug is administered,
that is a place where such an effect could have
occurred.

THE COMMISSIONER: I have forgotten
what quantity is there of lasix.



OD/BB/ak

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3 A. It would vary from child to
4 child and, again, I don't know how they were prepar-
5 ing it, so, I'm not sure.

6 THE COMMISSIONER: Surely the
7 chances, I don't know, the chances when you are
8 supposed to be administering it to an infant of
9 Lasix, will your chances be that you would administer
10 an adult dose of digoxin?

11 THE WITNESS: If you inadvertently
12 opened the adult vial of digoxin instead of the same
13 sized vial of Lasix, yes, you would substitute one
14 for the other. It is an unfortunate possibility and
15 things like this, again, unfortunately do happen.

16 THE COMMISSIONER: But would they
17 be likely to have these adult vials?

18 THE WITNESS: Yes. There were
19 multiple adult vials as well as pediatric vials
20 present on the ward during this whole time, at
21 least, that is my understanding. Again, I don't
22 know quantitatively how many but my understanding
23 is that there were a larger number of adult vials
24 present on the wards.

25 MR. STRATHY: Q. You are speaking of
adult vials of digoxin?

A. Of digoxin, yes, sir.



DD2

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3 Q. Well, we know for a fact that
4 there were patients in their teams Paul Murphy, for
5 example, was in his teens and was apparently
6 receiving digoxin as an adult.

7 A. Yes. I think there actually
8 are quantitative statements about how many vials of
9 each kind of digoxin were found on the ward at the
10 time and while I don't have the numbers there were
11 substantial numbers of adult vials of digoxin.

12 MR. STRATHY: Mr. Commissioner, this
13 is evidence of Dr. Costigan and the material that
14 was filed in relation to his search of the wards
15 and there were in fact a number of adult vials of
16 digoxin.

17 THE COMMISSIONER: So, you would
18 hope there would be more pediatric vials around
19 though than adult vials. I don't want to belittle
20 this theory and it is ingenious but I'm not
21 persuaded by it, that's all I can say. There are
22 so many things that seem to have to happen. First
23 of all, we have to get the wrong drug and then we
24 have to get the wrong dosage.

25 MR. ROLAND: Mr. Commissioner, I
think you may be labouring under a bit of a
misapprehension about adult and pediatric vials



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because, as Mr. Strathy has indicated, there are on this ward as well many older children and they would be receiving digoxin.

THE COMMISSIONER: Yes, but there are not many, at least - well, there may be, there may be, I don't know this for sure. Certainly the children with which we are concerned there were only two or three that were in their teens.

MR. ROLAND: That's true, that's true.

THE COMMISSIONER: Or over 10 - or over 2 for that matter.

MR. ROLAND: That's of the children we are concerned with. That is a very small proportion of the population of that ward at any one time.

THE COMMISSIONER: Is that a fact?

MR. ROLAND: Over a period of time there are a number of older children regularly on that ward.

THE COMMISSIONER: No, but you said there is a very small proportion of the ward, is that so?

MR. ROLAND: No, I don't have the figures on that or the demographics.



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THE COMMISSIONER: Well, anyway, what I would be far more interested in would be not the population of the ward but any different figures on the quantity of adults and pediatric vials where available.

MR. ROLAND: If you look at Exhibit 205 you will see from Dr. Costigan's inventory there were almost as many adult vials found on the ward as pediatric vials. All I want to indicate to you, Mr. Commissioner, that is not unusual. This is a pediatric Hospital but it is not unusual to find adult sized vials on this ward.

MR. STRATHY: Exhibit 185 is the inventory.

MR. ROLAND: 205 is the exact inventory prepared by Dr. Costigan himself.

MR. STRATHY: And 185 is Miss Rappaport's inventory.

You have in Exhibit 185, Mr. Commissioner, it indicates that you've got eight pediatric ampules and six adult ampules.

THE COMMISSIONER: Well, of course, we haven't got this diuretic, what's it called?

MR. STRATHY: Lasix.

THE WITNESS: Yes, that is furosemide,



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Mr. Commissioner.

MS. CRONK: Sir, that is part of
Exhibit 225.

THE COMMISSIONER: Yes. Which one
is that?

MS. CRONK: The brown one.

THE WITNESS: It is one of the
large brown ones, sir.

MR. STRATHY: And we have previously
had marked the pediatric and adult digoxin.

THE WITNESS: I think you may find
it helpful, Mr. Commissioner. The article from the
New York State Medical Society has a fair number
of descriptions of the types of vial confusions
which can occur among different medicines, including
some descriptions of digoxin being mistaken for
other medicines. That may be helpful as well.

THE COMMISSIONER: What exhibit is
this that you have just handed me?

MR. STRATHY: It is one of the
earlier ones.

THE COMMISSIONER: I have got 224 and
225 but we have these other ones.

MR. STRATHY: The other one is the
pediatric and adult digoxin.



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THE REGISTRAR: It is 131.

MR. STRATHY: 131.

THE COMMISSIONER: Yes, all right,
thank you.

MR. STRATHY: I am just referring to
Exhibit 185, Mr. Commissioner, that there were, on
4A, eight pediatric and six adult removed or found
and on 4B, 10 pediatric and 10 adult. So, it looks
as though the pediatric and adult ampules were
there in approximately equal amounts.

THE COMMISSIONER: Yes, all right,
thank you.

MR. ROLAND: Mr. Commissioner, this
may come out later in evidence but we have just made
a phone call to the Hospital to answer this question
for you, to assist you now because you are concerned
about it, and we are all concerned about it, and
it is our information that about half the children
receiving digoxin on the Ward 4A and 4B receive
pediatric dosages and about half receive adult
dosages.

THE COMMISSIONER: Well, isn't there
a gray area. I don't want you to keep phoning the
Hospital for advice every five minutes but I take
it a child doesn't just leap into adulthood.



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MR. ROLAND: Well, I presume there will be evidence about that but to give you a general guideline about the range of doses and I am sure that answer, or the answer to that question could probably come from Dr. Spielberg.

THE WITNESS: Yes. The issue would really be mostly with respect to the volumes of the drug that you would administer and the convenience and syringe types available. So that at some point you would like to switch over from a preparation that would require, say, several vials of pediatric or a whole vial of pediatric into a much smaller quantity of adult so that you can keep the volumes administered reasonably well. It would be a judgment matter made, based on the size of the patient and such, but I think it is very reasonable, given that the issue that we are trying to deal with is that where there are substantial quantities of such vials around my understanding was roughly half and half and I imagine utilization would be roughly in those kinds of percentages, particularly now since our population of children with congenital heart disease is getting older and older because more and more children are surviving into late childhood, adolescence and in fact adulthood. So, I am not



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2 at all surprised that that would be there.

3 THE COMMISSIONER: What is worrying
4 me about this of course is the fact that in certain
5 circumstances the injection of an adult vial of
6 digoxin could be fatal to a baby.

7 THE WITNESS: Yes.

8 THE COMMISSIONER: So that it becomes
9 - that's not any part of my mandate to consider
10 how the Hospital should operate itself but if that
11 is so and if you have adult vials around and if the
12 errors are as common as we seem to hear, that is a
very serious matter.

13 THE WITNESS: It is a very serious
14 matter. In fact, that is why the Hospital undertook
15 a tremendous effort to assure that the digoxin was
16 locked up.

17 THE COMMISSIONER: They didn't lock
18 it up until March the 20th.

19 THE WITNESS: That's true. But
20 subsequently we are not dealing with that kind of
a situation.

21 MR. STRATHY: Q. But, Doctor, isn't
22 that the point? I mean, as the Commissioner says,
23 Doctor, it is a very serious matter and what you
24 are telling us is that based on your experience from
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what you have seen it is certainly a possibility
that must be considered.

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A. Yes.

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Q. And must be considered

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seriously.

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A. Yes. In any non-unit dose

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system where multiple drugs are stocked on the

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floor and nurses have to make up the drugs adding

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to their responsibilities to the number of tasks

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that they have to do without the assistance of a

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pharmacist, in any non-unit dose system, be it here

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or any place, those kinds of risks indeed increase
dramatically.

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Q. Let me just, to deal with

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the Commissioner's concern, let me put one scenario

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to you as an example. Let us take a case of a

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child who is very sick at night, either in an arrest

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or just on the verge of an arrest, the doctor takes

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a look at the child and says, get me some epinephrine

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or get me some Lasix, panic, the child's close to

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death, big trouble, the nurse runs down to the

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medication room, runs up to the shelf, the medication

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is all on the shelf together and instead of taking

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that Lasix or instead of taking that epinephrine

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2 she picks up a vial of digoxin, confuses it for
3 whatever reason, fills up the syringe, takes it
4 back, the doctor is shouting for this syringe, what
5 is taking you so long and the doctor takes the
6 syringe and, whatever, doesn't check, administers
7 the drug to the child, administers digoxin or
8 Lasix instead of epinephrine.

9 As I understand what you are telling
10 us that is a scenario that you can see as a
11 possibility.

12 A. Can and does happen.

13 Q. And it can and does happen
14 in the arrest context as well, that is, in a
15 resuscitation effort?

16 A. Yes.

17 Q. You could have exactly the
18 same type of unfortunate scenario?

19 A. Yes.

20 Q. All right. Now, just to
21 turn briefly to Kevin Pacsai, and I think we have
22 already dealt with this, but you would view Pacsai
23 as an example of the pathophysiology in the same
24 general way as Gary Murphy; perhaps different
25 explanations for why it happened, but the same
general phenomenon?



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A. I have to be very concerned that that is the case from everything that we went through, both the clinical as well as the pharmacologic findings in the child, that has to be a major concern.

Q. And, indeed, if one accepts, and I'm not saying you have to accept, but if one accepts that Pacsai's pre-mortem level was close to 10, that would be explicable by your pathophysiology hypothesis?

A. Yes, and the numbers obtained post mortem and pre-mortem would be reasonably consistent with each other. Again, given that we have got lots of error all around those numbers, nonetheless, the numbers that we have, which is all we have to work with, are reasonably consistent with each other.

Q. The last child is Estrella. The only point I wanted to ask you about that is you have told us about your reservations about the possibility of an artefact and I wanted to ask you how you deal with the pre-mortem level of 9.4 which she had during life, although, well prior to her death. How do you explain that?

A. The best explanation I can



DD12

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3 see in the chart is the correlation of the high
4 level with a reasonably high blood urea nitrogen
5 at that time, again, BUN or blood urea nitrogen
6 being some measure of renal function. As best I can
7 tell with the chart, with continued administration
8 of the drug and some degree of renal impairment
9 occurring, be it pre-renal or actual kidney involve-
10 ment, that the drug would tend to accumulate during
11 that period of time.

12 Q. Does that fall within a
13 pathophysiological explanation?

14 A. That is more of a pharmacologic
15 explanation really in that the clearance of the
16 drug, or the half life of the drug, this beta half
17 life is going to be influenced by renal function
18 during that period of time. I think that is
19 probably the most reasonable explanation. One could
20 invoke a variety of other possibilities including
21 perhaps administration of a drug during that period
22 of time. I have no evidence for that. The only
23 evidence I have is the elevated BUN, which over the
24 next numbers of days came down as did the digoxin
25 level.



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Q. Now, lastly, in the Bain Report, Exhibit No. 48, Appendix 7, just let me ask you if you have seen this before, and specifically, paragraph 11 on page 56?

A. I have probably seen it. I do not remember it, frankly.

Q. Do you know who prepared it? It does not sound as though it was you because the author refers to you as Dr. Spielberg.

A. Again, I would be guessing. I think it is Dr. Bain, would be my guess. This is part of his addendum.

Q. All right. Let me read the last paragraph of that to you because it deals with the question of digoxin levels in exhumed tissue which is a concern with respect to some children. The author says:

"In the Vancouver study ..."
Referring to the evidence from the Hospital in --
Dr. Seccombe:

"In the Vancouver study the infants were all quite ill and were under three to six months of age. Levels of digoxin or digoxin-like substance went as high as 4.1. It is felt



"that the substance is a hormone manufactured in the adrenal and it is felt that it might be the sodium excreting substance (natriuretic substance). A Winnipeg paper shows that this substance may react for both the R.I.A. test and the H.P.L.C. test. The concept becomes important in that if there were a level of 3 to 4 nanograms in such children who are not on digoxin, then one might assume that the level in heart muscle might be 30 times that level or up to 120 nanograms. At least two of the babies in the present series had determinations done one heart muscle of babies whose bodies had been exhumed. They had not been embalmed. The time from death to exhumation was close to one year. Therefore, if there was any tissue left it must have been very dehydrated. If one assumes that 90% of the body is water, then there is a further factor of 10



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"which might be applied so that levels in heart muscle might well be as high as 1200 which is certainly higher than what was found. These are my own speculations. Certainly the hypothesis must be tested."

Now, as I read that, that is basically positing that the presence of "digoxin" in exhumed tissue may be explained by this endogenous substance; is that how you understand that?

A. That would be my understanding of the statement, yes.

Q. Now, whoever the author of this was, and I suppose we will find out when we hear from Dr. Bain, but whoever the author was certainly thought that that was a possibility. Would you go so far as to agree that that may be a possibility, that the endogenous substance may explain these levels?

A. As I indicated yesterday, with the data we now have available I would have to argue that the probability if one finds digoxin in those concentrations as been demonstrated in tissue, digoxin as measured by our techniques that we have available, is most likely digoxin or originating from



1
2 administration of digoxin.

3 As I indicated further, I might
4 have to change that opinion if more data come in with
5 respect to this compound.

6 Q. Let me stop you for a
7 moment. Do I understand when you say digoxin as
8 measured by our techniques, are you including mass
9 spectrometry as one of the techniques?

10 A. Yes, certainly identifica-
11 tion by mass spectrometry is a tremendously powerful
12 tool if it increases the likelihood dramatically
13 that it was digoxin. Still we have to accept that
14 until whatever the substance is is identified and
15 its mass spectrum determined, we cannot be sure
16 that they are going to be sufficiently different
17 that a mass spectrometer would pick up those
18 differences. Again, I am not an expert in mass
19 spectrometry at all, but certainly if the compound
20 is structurally sufficiently similar, it might
21 overlap.

22 The gap in that statement is the
23 presumption that whatever this substance is accumulates
24 in tissues similarly to digoxin. I am unaware of
25 any data at all on this issue. I gather that several
groups are actively involved in studying this.

Q. This substance being



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2 substance X so-called?

3 A. Yes, so that, for example,
4 the issue being brought up by that statement, which
5 I think is Dr. Bain's, is that if we are to accept
6 that postulate, we have to then accept the postulate
7 that the compound behaves in the body similarly to
8 digoxin and accumulates within tissues. We yet lack
9 those data.

10 Lacking those data, I have to fall
11 back on what data we do have and say that at the
12 present state of knowledge, exogenous digoxin is the
13 best explanation for the findings and I, as a
14 scientist, may have to change my impression if new
15 data come along. Presumably those data will be
16 coming along.

17 Q. Would it be fair to say,
18 though, that if it is exogenous digoxin, all you can
19 say is that there was digoxin in tissue and you really
20 cannot say what the significance of that digoxin is,
21 given the amount of time that has elapsed since death,
22 given the state of the tissues and so forth?

23 A. Yes, that is correct.

24 Q. And that would include,
25 I suppose, how it got there?

A. That is correct.



1 Q. And that would include, I
2 suppose, how it got there?

3 A. That is correct.

4 MR. STRATHY: Thank you.

5 THE COMMISSIONER: I am sorry, I
6 misunderstood. That last affirmative answer seems
7 to be contrary to what you said before. You said
8 in the present state of your knowledge at least you
9 know that it was probably digoxin, and digoxin can
only come from the outside.

10 THE WITNESS: I assumed, you know,
11 oral, IV, mistake, intentional. That was my response
12 to the question.

13 MR. STRATHY: Q. But you are not
14 able to say -- if I may?

15 THE COMMISSIONER: Yes.

16 MR. STRATHY: Q. But you are not
17 able to say really anything about how it got there?

18 A. No, I am not able to say
19 anything either about roots, intent or amount.

20 Q. Or indeed toxicity?

21 A. Yes.

22 THE COMMISSIONER: Yes, if that
23 is all that that meant, then that is ---

24 THE WITNESS: Yes, that was my
25 interpretation.



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2 THE COMMISSIONER: Well, we will
3 take a break, but before we do, Mr. Brown, I have
4 just been thinking, Mr. Sopinka is of course a bencher
5 so he is sitting in Convocation, is that right, he
6 is not appearing for someone?

7 MR. BROWN: I understand he is
8 sitting hearing a matter.

9 THE COMMISSIONER: But he is in
10 Convocation, did you say?

11 MR. BROWN: I am not sure whether
12 it is Convocation or simply a Disciplinary Committee.

13 THE COMMISSIONER: I know a fair
14 amount about that sort of thing, and if it is just
15 Convocation he is only one of 30 and he does not
16 need to worry about that; if it is a Disciplinary
17 Committee he is one of three or five and he can be
18 replaced.

19 Now, just suggest to him that he
20 has got to polish his excuses on that subject for
21 next Wednesday or whenever it was and see if he cannot
22 come up with a better story.

23 MR. BROWN: I will certainly
24 transmit that to him.

25 THE COMMISSIONER: Yes, all right.
Then we will take 15 minutes.



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2 ---Short recess.

3 ---On resuming.

4 THE COMMISSIONER: Mr. Hunt?

MR. HUNT: Thank you, Mr. Commissioner.

5 CROSS-EXAMINATION BY MR. HUNT:

6 Q. Doctor, my name is Hunt
7 and I represent the Attorney General and the Coroners.

8 A. Yes.

9 Q. Now, you have dealt in
10 considerable detail with drug administration error,
11 and I am going to restrict my questions to Justin
12 Cook's death.

13 We have heard evidence already with
14 respect to the availability of digoxin on Wards 4A
15 and 4B on the morning of Justin Cook's death, and it
16 came from Dr. Costigan. I just want to read that
17 evidence to you. It is relatively brief.

18 A. Certainly.

19 Q. It is in Volume 45, Mr.
20 Commissioner, at page -- it says 92. That does not
21 sound right, but that is what it says.

22 THE COMMISSIONER: Well, it is
23 possible. I have not yet enquired from the reporters as
24 to their numbering system, but it does change from
25 volume to volume.



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MS. CRONK: They started again.

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MR. HUNT: They must have started over. I missed that.

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THE COMMISSIONER: We perhaps ran out of numbers.

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MR. HUNT: Q. When Dr. Costigan was here he told us about his involvement in the events of the evening of March 21st, and he told us of a meeting that he attended about 10 or 11 o'clock involving Dr. Carver and what he did after that meeting. The one thing that he did immediately after was to, along with Dr. Mounstephen, go through the Hospital implementing new rules with respect to how digoxin was going to be treated. In doing so, he did an inventory of what he found, what he and Dr. Mountstephen found as they went through the Hospital.

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At page 92 about line 17 he is referring to that inventory and he says, and this is the question:

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"Q. Now, in the inventory that you prepared, it is perfectly clear that in many cases you found no digoxin at all either on the floor or on the cart?"

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And the reference was to the crash carts.



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"A. Yes, on 1, 2, 3, 4, 5, 6, 7
Wards.

Q. Yes, and I take it that
the inventory discloses that on
Ward 4B, and 4A, although the
parenteral digoxin preparations
were found in the medications room
no digoxin was found on the crash
carts on that floor.

A. Correct.

Q. Or on those wards, I am sorry,
but on 4C there was some on the
crash cart?

A. Yes.

Q. But 4A and B, the Cardiology
Wards, you found no digoxin on the
crash carts?

A. That is correct."

Then he went on to describe the procedure that
was implemented, which involved locking the digoxin
up in a medication cupboard or drawer, and he
discussed his conversations with Nurse Trayner who
was the team leader on the floor at that point.

Then at page 95 he was asked:

"Q. Did you stay to see the



1
2 "digoxin locked up on that floor?

3 A. Yes. My recollection is that
4 I went with the team leader and
5 we took the medications from their
6 usual place in the medicine room and
7 she put them into the locked
8 cabinet. I cannot remember seeing
9 the door actually closed but I was
10 present when she had the keys and
11 the door was opened so my under-
standing was that she had done that."

12 Now, the timing of that is not, I do not think, very
13 precise, but he went home by 1:30 in the morning, which
14 was some three and a half, four hours before Justin
Cook died.

15 A. Yes.

16 Q. Dr. Costigan was also
17 asked to comment, in the course of cross-examination,
18 on the medications that were normally found on the
19 crash carts on Wards 4A and 4B. At page 126, Mr.
Commissioner, he was asked the following question:

20 "Q. All right. Well, what is
21 normally on the crash carts on
22 wards 4A and 4B at that time?
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"A. Well, the crash carts are usually supplied in a relatively uniform fashion and the medications that they usually contain are things like bicarbonate, things like intravenous solutions, there is a drawer with all the equipment necessary for intubation, there is ampoules of adrenalin and ampoules of xylocaine or lidocaine as it is known.

Q. Are there any other standard medications you find on the crash cart in the fourth floor?

A. I am going back two years now. I mean, I don't think the fourth floor was really any different from any other crash cart anywhere else. Occasionally I think there would be some propanolol on the crash carts as well.

Q. Did you ever have occasion to see digoxin on the crash carts on Wards 4A, 4B?

A. In my experience before?



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"Q. Yes.

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A. No."

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Now, I think we also have evidence, and I do not have the precise reference here, to the effect that digoxin, it was felt, was not really appropriate for the crash carts because it was not the type of medication that would react sufficiently quickly or appropriately in those types of circumstances.

Now, having listened to that, sir, I am suggesting that in approaching this question of medication error, we really on the basis of the evidence, as I have indicated to you, have to start, do we not, with the assumption that as at 1:30 a.m at the latest on the morning of March 22nd, 1981, that digoxin was not on the crash cart in Wards 4A, 4B and that the digoxin that was in the medication cupboard had at that point in time been locked up pursuant to the new rules that were implemented. Would you agree that that is a fair starting point?

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A. I believe that every effort was made to accomplish that, and that an effort was made to assure that digoxin had in fact been so locked up. There are several pieces of information that would help us more to know what was happening with digoxin on the ward at that time.

Q. Just before you go on to that; in your evidence on October 24th, which is Volume 54, this was on your first day, at page 2158, you addressed this question of the probability of no digoxin being on the wards. I take it really we are referring to digoxin that was not, had not been locked up pursuant to the new regulations. You say, beginning about line 7:

"I think the possibility at least exists and has to be considered that, in the frenzy, number one, of trying to remove all the digoxin, some may have been missed."

Now firstly dealing with that, is there any evidence that you are aware of that the procedure that Dr. Costigan and Dr. Mounstephen undertook with respect to digoxin was in any way frenzied?

A. I am sure that it was very



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stressful, given what was going on.

Q. All right. So would we substitute "stressful" for "frenzy"? Because you see the two really do connote quite different states?

A. I would imagine, and again imagining what kind of stress people are under under circumstances like that, that most physicians asked to quickly sequest a lot of drugs and make sure there were none around in as rapid a fashion as possible, because of the possibility of a lot of problems going on in that ward, would be acting in a manner that: "number one, that they were unaccustomed to; number two, under a great deal of stress; and number three, since typically physicians are not used to doing drug inventories, pharmacists are used to doing drug inventories, that if I were asked to do that under those same sort of circumstances I would be somewhere between concerned and frenzied, yes.

Q. So basically though you are speculating on all of that?

A. There is a good deal of information on errors made by physicans versus pharmacists in doing inventories, however, physicians make more errors.



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Q. If I can come back from the sort of literature and the reported incidents back to this one that we are dealing with.

A. Yes.

Q. You are speculating with respect to what happened with Dr. Costigan and Dr. Mounstephen?

A. We are speculating that the possibility exists that a dose was missed.

Q. You are speculating?

A. Yes.

Q. And you would, insofar as the atmosphere is concerned, I take it of necessity defer to Dr. Costigan and Dr. Mounstephen?

A. Yes.

Q. So the possibility, and you put it as a possibility, as a speculation, that a dose may have been missed, is one that we have to consider.

A. Yes.

Q. So we are dealing are we not then, after 1:30 a.m. on March 22nd, with a situation that insofar as resuscitation is concerned we have evidence that there was no digoxin on the crash cart, supported by evidence that there never was any on



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that crash cart. We are dealing with a drug that we have heard in evidence is not really appropriate for a crash cart in those circumstances in any event.

A. Albeit that digoxin had remained on adult crash carts at the Hospital for a very long period of time.

Q. We are talking about 4A and 4B this time, is that a fair assessment?

A. I believe everybody felt it should not be on the cart.

Q. Now I was somewhat confused by your evidence, and I don't suggest that is your fault, believe me, with respect to the effect that you felt the efforts of Drs. Costigan and Mounstephen would have had, or might have had on the possibility of medication error.

I am going to just read to you a portion that I am concerned about.

A. Yes, sir.

Q. And we can talk about it. I will just back up a little bit from where I was reading before, Mr. Commissioner, page 2158 in Volume 54 starting at the top of that page, and this is your response, sir.

A. Yes.



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Q. "Now, the probability of
no digoxin being on the ward, which,
I mean to say, no digoxin has to at
least been questioned somewhat again
from experience of the similarity of
vials and the situation on the ward
at the time.
I think the possibility at least
exists and has to be considered that
in the frenzy, number one, of trying
to remove all the digoxin, some may have
been missed.
Is this impossible? Not in the least,
in my mind, given what happens when
these events are occurring in a complex
and, at that time, rather sad ward.
Looking for all the digoxin and trying
to make sure there is none there, a
vial conceivably could have been
missed.
If a vial were missed under those
circumstances, the probability of a
medication error goes up dramatically
in this child because the expectation
is that there is not going to be any



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"digoxin around. Therefore, when one looks down at labels which are written in extremely small sizes and which, frankly I - and I know of no other physician who has not misread some labels, particularly at the time of an arrest. If some digoxin were around, the probability of an error is increased because no one expected it to be there."

Now frankly, sir, I suggest to you that doesn't follow from the events that we have seen preceded this incident and from the drug that we are dealing with.

Let me just put this to you and this will explain my concern and then you can comment on it. If digoxin is not normally an appropriate drug to be on a crash cart in those situations; and if it is not known to have been on it prior to this occasion; and if there is concern about it being available in other than a controlled situation and steps have been taken to lock it up, it seems to me that that can't possibly increase the probability of an error with respect to digoxin.

A. What I meant to say, and perhaps I will try to clarify it a little bit; is



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2 that number one, people were concerned I believe
3 about digoxin and this is why the digoxin was being
4 locked up. And as such the expectation was that
5 certainly there would be none around. The expectation
6 was probably that on the crash carts prior to this
7 none would be around, but people were now having a
8 heightened concern with respect to digoxin. And yet
9 when it is locked up, well now you expect there to
10 be absolutely none around.

11 In the situation where you pick up
12 vials I, just like everybody else, the brain takes
13 a look at something and says, well, this can't
14 possibly be the case, before it was very unlikely to
15 be the case, now my mind tells me there cannot be
16 any digoxin around. I look down at a vial and I
17 misread it to an even greater extent. It sounds
18 strange but that is just what happens on the wards
19 during urgent situations.

18 Q. Well ---

19 A. And you look down and you
20 say, no, it is all locked up, it can't possibly be,
21 so you ignore the label and move even more rapidly,
22 because you can't accept the fact that there is any
23 there.

24 Q. But, sir, in this situation
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3 are we not dealing with a drug that normally nobody
4 is going to be looking for in any event in those
5 situations?

6 A. Exactly, but if you saw it
7 before you might well say, gee, maybe it snuck on
8 here in some way, I know that there is lots of it
9 around. Here you have a situation where your mindset
10 is such that you are convinced there is none around,
11 which means your mind is going to even more reject
12 the possibility that such a vial would be there,
13 and as such you would reject the idea more readily.
14 Again that sounds strange, but in the situations on
15 the wards where urgent events occur it is not all
16 that uncommon.

17 To give you an example, at another
18 institution I worked at we had two different kinds
19 of calcium, calcium chloride and calcium gluconate.
20 The concentrations are different, this is not here,
21 this is at another institution. A decision was made
22 to get rid of all the calcium chloride so we would
23 only have one salt available in the nursery because
24 of the chloride load. We did however, again miss
25 some calcium chloride and people were making
mistakes with it. Because again we expect the
calcium gluconate to be there. How probable that is



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in an urgent situation I can't tell you for sure.

I know that these happen, and I know that the mindset of people fully expecting there to be none around increases the probability that if it is your mind is going to reject it, that's it and you move on to something else.

Q. Is it fair then, sir, that that is what you were referring to, that the mind set of somebody may increase the probability of an error?

A. Yes.

Q. But will you agree with me that along with that you are going to have to also consider the nature of the drug that was being used, whether or not it would have been there before in any event so people would be looking for it; and the fact that steps were taken to see that it had been removed and apparently it had.

A. The two additional things we need to know about removal are the following.

Was any digoxin actually used on any patient on the ward after it was locked up? In other words, had any digoxin been taken out.

And two, we know that medication borrowing was going on on the wards. This is a



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3 procedure that obviously now has been stopped. The
4 question exists, given that syringes were being
5 brought in with labels on them without the original
6 vials, which is a practice which fortunately has
7 indeed been stopped in the Hospital, could that have
8 originated from another source.

9 So that we have several potential
10 ways that digoxin could have been there: one a vial
11 simply was missed on a shelf or some place else.

12 Two, that in fact the medicine cabinet
13 but it had been opened for digoxin, or for another
14 purpose. For example, for morphine which we know
15 that he got, and morphine is locked in the narcotics
16 cabinet, and we know that Justin Cook received a
17 dose of morphine, an appropriate therapeutic agent
18 for a tetralogy spell. Or that the drug arrived
19 from another ward because drug practices at that
20 time were accepting of the possibility of a drug
21 arriving from another ward.

22 Now I don't know, and obviously
23 Dr. Costigan can tell you, or one of the nurses on
24 the ward, whether the digoxin was locked up with
25 the morphine. Because if the digoxin was locked
up in fact in the narcotics cabinet, which is the
most likely place it is locked on the ward, we know



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that the narcotics cabinet at least had to be entered for Justin Cook and may have had to be entered for other patients, which leaves the possibility of an error being made.

Q. What I am trying to get clear here is your use of the word "probability" and suggesting that it increases. I want before we leave this to be very clear. You have just said, I understand, you are not saying that after all of these precautions had been taken, given that there may never have been any on the crash cart in any event, that the probability actually does not increase but the fact that someone may have a mindset with respect to its absence that factor may increase the probability if other factors combined in sufficient circumstances to render it at all possible?

A. Yes.

Q. All right.

A. That and the overall atmosphere on the wards which again given the circumstances must have had some influence on the way people were performing at that time.

Q. If you are going to consider the overall circumstances on the ward don't you also have to consider that now the doctor on the ward



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had a heightened sensitivity with respect to digoxin, and in addition to that, if I can direct you to page 30 of Justin Cook's chart, Exhibit 116: well perhaps I will just indicate it to you.

A. Yes.

Q. This is the list of drugs that Justin Cook received during the arrest procedure. Now it is signed by Dr. Mounstephen. Would that suggest he was the one who was present and was keeping a list?

A. I would assume, unless it was transcribed from one of the nurses who was keeping the list.

Q. Well assuming that he was present and kept the list?

A. Yes.



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Q Now, in addition to the fact that the doctor, the clinician who was present had a heightened sensitivity, we have present one of the very doctors who went through the Hospital ensuring that the digoxin was locked up. When you add those factors to all the circumstances, it really begins, does it not, to make the likelihood of digoxin, those circumstances combining to make the digoxin available rather smaller?

A Except that Dr. Mounstephen made a medication error on that list. He did not list the drug given to the child, Lidocaine.

Q How do you know that was given to him during the resuscitation attempts?

A There is no other time that it is listed any place.

Q Well, now, wait a minute.

A The concentration ---

Q Well, with a medication error it can be a medication error before ---

MR. ROLAND: Will Mr. Hunt please let the witness finish his answer.

MR. HUNT: Well, I would like to try to ---

MR. ROLAND: He asked how do you know and the witness was giving his answer.



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MR. HUNT: Yes. I would like to try to keep it focussed somewhat more, so, I may cut you off from time to time.

THE WITNESS: Sure.

MR. HUNT: And my friends will object and we can do it on a question by question basis.

MR. ROLAND: Well, there were two parts to that.

MR. HUNT: And the doctor gave one part of it and he was stopped from giving the other part.

THE COMMISSIONER: All right.

MR. ROLAND: He should be allowed to give the other part.

THE COMMISSIONER: Doctor, if you remember the question or if you remember the qualification that you wanted to make will you make it now.

MR. HUNT: Q. Well, let us remember one other thing, Doctor. You have just said that Dr. Mounstephen made an error. I want you to address yourself to that.

A. Yes. The probability, given the clinical circumstances, and I am assuming that the drug was used for therapeutic indications, no there was no therapeutic indication for the use of Lidocaine



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in the child before that and there was a good therapeutic indication for the use of Lidocaine for the child during the arrest procedure when he was in ventricular fibrillation. He was not in ventricular fibrillation prior to that. If the drug was indeed being used correctly and the plasma levels found were therapeutic levels then the drug most likely would have been given during the resuscitation attempt.

Q. So, you are speculating based on that evidence?

A. Yes.

Q. So, it may be that Dr. Mounstephen didn't make an error?

A. It is likely in my opinion that the drug was given during the resuscitation and was not listed on that sheet.

Q. It may be that it wasn't given during the resuscitation and therefore need not have been listed?

A. I think that possibility is remote.

Q. Now, in any event, we have Dr. Mounstephen there apparently who has not been involved very much with digoxin on that particular evening.



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A. Yes.

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Q. All right. Now, if I have

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taken from your evidence to date with respect to

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resuscitation that what happens is somewhat chaotic,

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frenzied and perhaps undisCIPLINED to a degree,

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would I be wrong?

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A. It varies greatly and it often

is.

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Q. It often is what?

10

A. Frenzied.

11

Q. Frenzied, chaotic and undisCIPLINED?

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A. Yes.

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Q. All right. Now, when was the

14

last time that you were involved in the resuscitation
team at Sick Children's Hospital?

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A. I have not been involved in a

16

resuscitation team at Sick Children's Hospital.

17

Q. All right. So, you can't really

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help us with any experience from that?

19

A. No, sir.

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Q. All right. Well, happily for us,

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Dr. Costigan can because he was very much involved
with that and I just want to put to you what

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Dr. Costigan has told the Commission about that.

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Mr. Commissioner, I am referring to Volume 46, at

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page 246.

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GG.5

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2 MR. STRATHY: Before my friend
3 proceeds, Mr. Commissioner, there is a matter that I
4 think is only fair to point out. I am comparing the
5 chart - this is Mr. Brown really who is the sleuth
6 here - comparing the chart of Cook that my friend
7 has been referring to in the list signed by
8 Dr. Mounstephen and also the chart of Inwood.

9 THE COMMISSIONER: What number is
10 Inwood, please?

11 MS. CRONK: Exhibit 113 is Inwood.

12 MR. STRATHY: 113 is Cook.

13 MS. CRONK: No, 116 is Cook.

14 THE COMMISSIONER: 116 is Cook?

15 MR. STRATHY: And 113 is Inwood. So,
16 if you go to page 30 of Cook, which my friend has
17 been referring to, page 62 of Inwood, if you look at
18 page 30 of Cook the writing on that page compared
19 to the, about three-quarters of the way down page 62
20 of Inwood, it looks, at least to my eyes, as though
21 it is a different handwriting and what may well have
22 happened on the Cook arrest is that a nurse filled
23 in the list and it was signed by Dr. Mounstephen who
24 was in attendance. Certainly it is my understanding
25 that the practice is that the list would be made up
by a nurse and not by a doctor and given what we have



GG.6

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2 seen about doctors' writing on charts it sounds as
3 though any time there is going to be writing by and
4 large the nurses do it.

5 MR. ROLAND: Mr. Commissioner, that
6 is the practice as I understand it in the Hospital.
7 The doctor of course is administering the drugs and
8 isn't recording the administration. It is one of the
9 functions of either a member of the arrest team or
10 someone who is there present at the time of the
11 arrest from the medical staff who will be recording
12 the drugs given. It is certainly not one of the
13 functions of the doctor at the time, he signs it but
14 he is busy administering the drug and issuing it to
15 the patient.

16 MR. HUNT: He is part of the chaos.
17 Well, I don't think anyone is suggesting Dr.
18 Mounstephen wasn't there and I suppose that was really
19 the point that I was making that we had someone there
20 who had been intimately involved with it.

21 Q Now, if we go back to where we
22 were. Yes, you had commented on the resuscitation
23 procedure and I indicated Dr. Costigan, who was the
24 chief resident during this period and had assisted
25 with respect to the resuscitation procedure and in
the course of this I think he will indicate what his



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own involvement was on these, but I am looking at
page 246.

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THE COMMISSIONER: Of?

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MR. HUNT: Oh, I'm sorry, Volume 46.

6

Q This is from the cross-examination
of my friend Mr. Olah, beginning at about line 15:

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"Q From what I understand, Doctor,
these Code 25's are fairly well planned
and carried out. Many people have
assignments and there is a sequence
to carrying out the procedure?

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11

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"A. Yes.

13

14

"Q For instance, there is a nurse
designated to draw up the drugs?

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16

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"Q And there is a nurse who is
designated to take notes as the arrest
procedure is carried out?

18

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"A. Yes. She takes down timing of
things.

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"Q And the drugs that are being used;
and other nurses are assigned to carry
out pulmonary resuscitation; so that
there is a set procedure?

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"A. Yes.



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"Q. I think you said yesterday in your examination that in fact some drugs are pre-drawn?

"A. Some drugs are actually prepared by the manufacturer in pre-filled syringes.

"Q. Can you recall, I think you went through this with Miss Forster, was adrenaline one of the ones that was in a pre-drawn syringe?

"A. The situation is that as time has gone on more drugs have become available in pre-drawn syringes and I cannot recall at that time which medications were available in pre-drawn syringes.

"Q. Now of course drug error is something that you have mentioned as a possibility, and one that is always sought to avoid. Is there some procedure whereby the nurse that is drawing up the drug holds up the vial and shows it either to the doctor or the nurse who is recording it to demonstrate that the right drug is being drawn up?



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"A. Yes, it is shown to the person who is going to administer the medication. It is usually the doctor.

"Q. That is the doctor. Would that be you, when you are heading up the team?

"A. In most instances, yes.

"Q. I don't know if you can recall, but in all of the cases that you attended, was that procedure carried out, namely that the vial was held up, shown to you to be the right vial, before the injection occurred? Was that your usual procedure?

"A. Oh, yes, that is my usual practice, yes.

"Q. So, we can be fairly clear, doctor, I take it that drug medication error did not occur during arrests while you were in charge of those teams?

"A. Yes. The drugs that I administer I always check that the drug is what is on the vial.

"Q. So not only the nurse that is drawing it up checks it but there is



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"a double or a safety precautionary
check by the team leader?

"A. That is my practice - my practice."

"Q. Thank you. In the discussion
of confusion of medication, Dr.
Costigan, Mr. Olah this morning asked
you about the arrest procedures and
the devices and techniques that you
have for assuring, or doing the best
you can to ensure, that medication
errors do not occur?

"A. Yes.

"Q. And the vial being provided to
you with the syringe and so on so that
you may check?

"A. Yes.

"Q. We have heard a good deal about
arrest procedures and the picture I
confess that we have had, Dr. Costigan,
is one of intense activity at the
bedside. Is that fair? Things happen
pretty fast?

"A. Yes, there is urgency.

"Q. Urgency of course, and presumably
a stressful situation, whatever that



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"may mean. That word has been used to describe the situation. Do you agree with it?

"A. I guess, yes. It depends on one's appreciation and one's prior experience, and multiple factors, really.

"Q. You referred to training of the arrest team in arrest procedures.

"A. Yes.

"Q. Do I take it that no matter how hurried and perhaps frenzied the appearance may seem to be it is not chaotic and it is not undisciplined?

"A. That is correct. It should not be chaotic or undisciplined.

"Q. Indeed, I take it the very urgency of the situation makes it the more important to have procedures and routines and training to avoid errors taking place in such a context?

"A. Absolutely, yes."

And then completing his answer with respect to that at page 359:

"Q. I take it, therefore, that although



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"the room in which resuscitation effort
is occurring may be full with people
watching what is going on --

"A. Yes.

"Q. And anxious to help if they can,
those directly involved in the
operation know what they are about;
they are trained in what they are about,
and the appearance of chaos does not
reflect the reality of chaos. Is that
fair?

"A. Yes, there is really a very
limited number of people who actually
touch the child. The usual situation
is that there is a nurse doing the
external cardiac massage. The
anaesthetist arrives and takes over
the management of the airway. The
surgical resident who is quite an
expert in getting intravenous has
arrived and his job - and has a nurse
assisting him, is to find a good
intravenous line so medication can be
given.

"The role of myself or the associate



GG.13

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"resident is to make sure that everybody is doing what they are meant to be doing, to read the strips from the cardiac monitor, to diagnose the phase, to give medication, to judge the response, to give more medications, to carry on that way.

"Really, even though there are other people around, their actual involvement should be minimal, really."

Now, Doctor, the picture that Dr. Costigan has given to us of the arrest procedure, the resuscitation procedure, would you agree with me is certainly not one of undisciplined, frenzy or chaos?

A. That is an ideal description of an arrest, yes.

Q. Well, of course, he was involved in some of them?

A. Yes.

Q. I think you heard his evidence?

A. Yes, I have been involved in hundreds as well. Ideally they go that way; many do not.

Q. All right. But unfortunately



GG.14

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2 you haven't been involved with any at the Sick
3 Children's Hospital so that we don't have the
4 benefit of your experience there?

5 A. There are several other points.
6 Epinephrine was not available in pre-loaded syringes
7 at the time and most other medications in fact were
8 not as well. Again, all we can rely on, since we
9 cannot rely on error figures at The Hospital for
10 Sick Children under such circumstances or error
11 figures under such circumstances at other institutions
12 which is high and, furthermore, the procedures are
13 not as uniform as suggested. If one looks through
14 several hundred resuscitation charts managed by
15 different physicians in the Hospital, doses vary,
16 amounts vary, orders vary. None of them are wrong.
17 At the Academy of Paediatrics, Committee on Drugs,
18 we reviewed resuscitation procedures in general and
19 found recommendations varying in different
20 institutions and different parts of the world; tenfold
21 differences in epinephrine recommendations, large
22 differences in calcium recommendations, all of which,
23 depending on who's there, their prior training, their
24 prior experience, can vary dramatically.

25 I think Dr. Costigan describes a very
good picture of what an ideal arrest would be like



GG.15

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2 with an orderly, straightforward kind of thing
3 happening.

4 Recognizing that we are dealing
5 nonetheless with perhaps 20 or 30 administrations of
6 medication, which were not available in pre-drawn
7 syringes at that time for the most part, which
8 required extra effort similar to the situation that
9 I faced when I was a house officer involved in
10 running similar types of arrests, given the number
11 of drugs, given everything we know about errors and
12 given the fact that having observed many arrest teams
13 where exactly the same orders applied, looking at
14 the vials and everything else, procedures break down
15 despite how hard we try, procedures broke down worse
16 at night than during the day when people are not
17 as fresh. Procedures break down when stress goes up.

18 Thus, an ideal description in the real
19 world I'm afraid it's not a very apt description of
20 arrests as a whole.

21 Q All right, thank you, In any
22 event, we have Dr. Costigan's experience in the
23 evidence and you have no trouble with us relying on
24 his experience?

25 A. I think it's naive.

Q. Pardon?



GG.16

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A. I think the statements are a

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bit naive.

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Q. I see. So, Dr. Costigan is naive?

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A. Not intentionally so or, you

know, malevolently so.

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Q. Yes.

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A. But naive to what in general goes

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on under such circumstances.

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Q. Yes.

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A. Most physicians in fact will,

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generally speaking, and most hospital staff will,

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generally speaking, deny medication errors. In fact,

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when one presents the data accrued from good

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surveillance studies, most doctors and nurses will

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say it's impossible, it doesn't happen. When one

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does the studies, not only is it possible, it does

happen.

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Q. So in your view in assessing Dr. Costigan's account we should consider that it is naïve and we will have to make our overall assessment taking that into account?

A. I think one has to take into account that indeed many arrest procedures, even under ideal circumstances, are error prone and difficult and that an ideal description, and in fact perhaps most of the arrests that Dr. Costigan ran were done like that. I think that is a very good possibility. But he said repeatedly that is my usual practice to look at vials. I am sure there are times that he, like any of us, did not. It happens. That is the real world, and the real world is what we have to deal with.

I am sure he made every effort to do that every time he went to a resuscitation. I am sure he made every effort to keep it orderly every time he went to a resuscitation. We all do; we all try our best, and yet those circumstances are tremendously difficult and stressful and variable, and I would posit particularly with the circumstances on the ward at that time. I cannot imagine anyone feeling very cool and calm and organized when Justin arrested.



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Q. Well, when we come to examine the various possibilities or hypotheses that you have posed and we come to consider your hypothesis of a drug administration error during the arrest, we can take into account all of this that we have just been discussing with respect to the availability of digoxin and the procedure as it is followed during the arrest?

A. Yes. I certainly do not know what happened that night, whether he received the dose by accident or by intent. I believe very strongly that we have to at least strongly consider the possibility of an error having been made in the system.

MR. HUNT: I just plan to keep going if that is satisfactory with you?

THE COMMISSIONER: That is fine with me. Mind you, some time around 9 o'clock I will call a halt.

MR. ROLAND: Mr. Commissioner, the only consideration, and I am not criticizing anybody, but we tend to forget the witness in this exercise. We think of our own convenience.

THE COMMISSIONER: Well, I am partly thinking of the witness because I am concerned that --



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you will excuse my using the expression -- we dispose of you by tomorrow night.

MR. ROLAND: He would very much like that as well, but you should know that the witness also gets very tired in this long exercise. He is working in a sense harder than the rest of us, and unfortunately, Dr. Spielberg has a young son himself and a wife who have not been well lately and he has not been getting much sleep, and this exercise is very tiring for him.

THE COMMISSIONER: Well then, I take it, you would be in a difficult position if you disagreed with anything your counsel has said.

THE WITNESS: I have slept poorly on many nights.

THE COMMISSIONER: Well, usually that is a sign of old age and you certainly are not in that position yet.

THE WITNESS: It has been a sign of nighttime responsibilities.

MS. CRONK: Under the circumstances, sir, might I suggest, I am conscious both of the concerns of the witness and the potential timing problems, that we stop now for this evening and if necessary, we continue a little later tomorrow



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should it prove necessary, and I am hopeful that indeed it will not be the case.

THE COMMISSIONER: Well, we may have the same problem tomorrow that we have tonight.

MR. HUNT: I can probably finish up relatively quickly.

THE WITNESS: I trust I can get a night's sleep tonight.

THE COMMISSIONER: Well, that is fine, Doctor, you depart now and we will discuss timing. We will see what the amount of timing is, and I may -- I know that it is not a policy that I have adopted myself, but we might just have to limit the cross-examination. How long do you think you will be, Mr. Hunt?

MR. HUNT: I could finish up quite shortly now even.

THE COMMISSIONER: Well, apparently you are not going to be given that opportunity.

MR. HUNT: Well, 10 minutes, 15 minutes.

MR. YOUNG: I have no questions, Mr. Commissioner.

THE COMMISSIONER: Still no questions?

MR. YOUNG: No.



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THE COMMISSIONER: Mr. Ortved?

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MR. ORTVED: I have no questions.

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THE COMMISSIONER: Miss McIntyre?

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MS. MCINTYRE: Well, I had predicted

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15 minutes, but I may be longer than that. Certainly

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I do not think longer than half an hour.

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THE COMMISSIONER: Miss Jackman?

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MS. JACKMAN: Mr. Commissioner, I

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either have no questions or at the most it would be
about 15 minutes.

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THE COMMISSIONER: All right.

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Mr. Olah?

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MR. OLAH: I still have 15 minutes,

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Mr. Commissioner.

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MR. LABOW: I expect to be about

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20 minutes, Mr. Commissioner.

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MR. TOBIAS: Mr. Commissioner, I

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expect to be about half an hour, but I do want to
point out I control the length of time it takes me

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to put the question; I have no control over the

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length of time that the witness takes to answer the
question.

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THE COMMISSIONER: Well, I think you

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have to bear in mind the witness when you say how

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long you will be.

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HH5



HH6

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MR. TOBIAS: Well, bearing in mind the witness, can I then increase my estimate to about 45 to 50 minutes.

THE WITNESS: I shall struggle for brevity as well.

THE COMMISSIONER: Mr. Shanahan?

MR. SHANAHAN: If I have any questions, sir, I shall be over in about 10 minutes.

THE COMMISSIONER: We cannot get an estimate from Mr. Shinehoft. That is 35 minutes. Well, I am going to go through some kind of formula. I am not going to hold you to the times that you have said, but I am going to hold you to something fairly close to it because we are going to have some trouble finishing tomorrow if I do not. So I want you to bear that in mind. Mr. Tobias, I certainly will hold you to 50 minutes, so I want you to work from it, and I am not going to allow anyone to go more than that, and those people who have been good enough to say that they will have no time at all, twice zero is zero, and even if I allow you double time I do not think you will be able to work it in.

So I have now got a commitment out of you and I will also get a stopwatch, and we will



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see what happens tomorrow. So 10 o'clock tomorrow morning.

---Whereupon the hearing adjourned at 4:40 p.m. until Thursday, October 27th, 1983 at 10:00 a.m.

